# EPA Reg. No. 75526-1
# Vol. 1

# Material to be added to a Mini-Jacket
## (in the case where an e-Jacket exists)

**Reg. No. 75526-1**

**Send to SIG: check box** [X]

This material is:

**New stamped-accepted label**
New CSF
Notification
Final Printed Label
€ Other:

**Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).**

**Reviewer's Name: Martha Terry**

**Phone: 703 308-6217 Division: AD**

**Date: 10/5/2006**

Current as of July 12, 2006



SIG
11/1/06

DECISION PKG. NO. 356769 SUBM. DUE DATE 8/2/06

SUBMISSION BAR CODE # 797382 REVIEWER MT

# CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 75526-R PM 33 ACTION CODE A-46

DESCRIPTOR New Labels FQPA NFQPA

[ ] CHILD RESISTANT PACKAGING: [ ] REQUIRED [ ] NOT REQUIRED

REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL [ ] RESTRICTED USE

| DATE ON APPLICATION | EPA RECEIVE DATE | PM RECEIVE DATE |
|---|---|---|
| 8/02/06 | 8/02/06 | 8/02/06 |

METHOD OF SUPPORT

[ ] CITE-ALL [ ] SELECTIVE
[ ] NOT SUBMITTED [ ] N/A

FORMULATORS EXEMPTION

[ ] SUBMITTED [ ] NOT SUBMITTED
[ ] N/A

| REVIEW(S) REQUESTED | DATA PACK # | DATE SENT | DUE DATE | DATE RETURNED |
|---|---|---|---|---|
| CHEMISTRY | | | | |
| EFFICACY | | | | |
| ACUTE TOX. | | | | |
| RASSB TOX. | | | | |
| ENVIRON. FATE | | | | |
| FISH/WILDLIFE | | | | |
| OTHER: | | | | |

STATUS

RESPONSE CODE 1170 RESPONSE DATE AUG 18 2006

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:
x Registration
___ Reregistration

(under FIFRA, as amended)

| EPA Reg. Number: | Date of Issuance: |
|---|---|
| 75526-1 | AUG 18 2006 |

Term of Issuance: **Conditional**

Name of Pesticide Product: Stalosan F

Name and Address of Registrant (include ZIP Code):

ArchAngel LLC
636 Hampshire, Suite 208
Quincy, IL 62301

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Revise the "EPA Registration Number to read, "EPA Reg. No. 75526-1".

Signature of Approving Official: M Swindell

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date: AUG 18 2006

EPA Form 8570-6

b. The Enforcement Analytical Method stated under MRID #465388-01C is not acceptable. A new Analytical Method must be submitted, reviewed and found acceptable by December 31, 2006.

3. Submit two (2) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

[bracketed phrases are optional text]

# Stalosan F

**For use in livestock housing, to improve the external environment and flooring conditions around animals.**

Lack of moisture assists in the reduction of non-public health microorganisms
**Stalosan F** adsorbs moisture, ammonia, hydrogen sulphide and other gases.
[Inhibits the growth of non public health bacteria and fungi]
[Eliminates odor causing bacteria, fungi, mold, and mildew]
[Inhibits the growth of non public health bacteria]
[Inhibits the growth of non public health fungi]
[Reduces ammonia and moisture]
[Eliminates odor causing bacteria, fungi, mold, and mildew]
[Eliminates odors associated with bacteria, mold, and mildew]
[Deodorizes], [Deodorizer]
[Controls and inhibits odor causing bacteria, fungi, mold, and mildew]

Active Ingredients:

| | |
|---|---|
| Copper Sulfate Pentahydrate* | 2.66% |
| Inert Ingredients | 98.54% |
| TOTAL | 100.00% |

* Metallic Copper Equivalent Equal-----0.68%

ACCEPTED
with COMMENTS
EPA Letter Dated:
AUG 18 2006
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.
75526-1

## Caution

Keep Out of Reach of Children

### FIRST AID

**If in eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 75526-R

EPA est. No. 75613-DNK-01

ArchAngel LLC
636 Hampshire, Suite 208
Quincy, IL 62301
phone number 217-641-0007

**25 Kg. Net Wt.**

# PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.



# ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic organisms.

# Directions for Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

**Application methods**: Limited application can be conducted by utilizing a hand cranked, spreader or duster device. When using a hand crank device, carefully deposit product from the bucket or bag into the hopper of the device using a measuring cup consistent with recommended application rates. For more extensive applications, use an electric or gas powered blower unit capable of blowing 300 – 400 cubic feet per minute. Select blowers that have vacuum capability. Determine the amount of product needed for the area of application and pour directly from bag or bucket into a temporary storage container. Use the vacuum attachments which come with these units to draw up material directly from the temporary storage container. Due to the likelihood of dust in the air, use safety goggles and a dust mask when applying with blower units. Clean up any spillage during application and dispose of according to disposal instructions shown below.

**Dosage rates:** Add 1 pound of **Stalosan F** to every 100 sq. ft. If the area is badly affected, increase the dosage slightly. Initially apply **Stalosan F** once a day for 3 days. Continue treatment once a week, thereafter. **Stalosan F** can be applied while animals are present.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in a cool, dry area away from direct sunlight and heat to avoid deterioration and in an area inaccessible to children.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Once bag is empty, dispose of in a sanitary landfill or by incineration, or; if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Decision #: 356769

# DATA PACKAGE BEAN SHEET

DP #: (322901)

Date: 26-Oct-2005



## * * * Registration Information * * *

**Registration:** 75526-R - STALOSAN F

Company: 75526 - ARCHANGEL LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# CM-2 308H

Risk Manager Reviewer: Martha Terry MTERRY

Sent Date: _____ Calculated Due Date: 20-Aug-2006 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A46) NEW USE;WITH EXEMPTION;NEW FOOD USE;

Ingredients: 024401, Copper sulfate pentahydrate(2.66%)

## * * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 26-Oct-2005 Due Back: _____

DP Ingredient: 024401, Copper sulfate pentahydrate

DP Title: Product chemistry for new appl

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #: _____

| | Assigned To | Date In | Date Out | |
|---|---|---|---|---|
| Organization: | AD / PSB | 10/27/05 | | Last Possible Science Due Date: 07-Apr-2006 |
| Team Name: | CTT | 10/27/05 | | Science Due Date: 7/20/06 |
| Reviewer Name: | [signature] | 11/15/05 | 6/16/06 | Sub Data Package Due Date: 7/4/06 |
| Contractor Name: | | | | |

## * * * Studies Sent for Review * * *

No Studies

## * * * Additional Data Package for this Decision * * *

Printed on Page 2

## * * * Data Package Instructions * * *

Please review the chemistry package for this new aplication. Enclosed are the label, CSF,and chemistry data: MRID# 46538801, -02, -09

This application is being reviewed in conjunction with a Tolerance Exemption Petition 5F6982 for use in livestock premises.

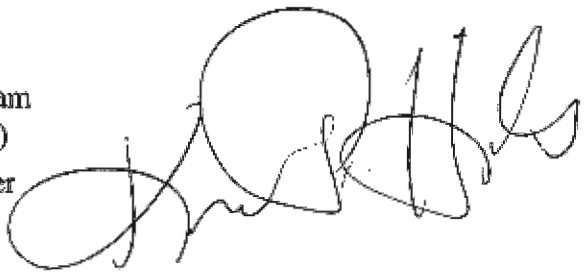
**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**Washington, D.C. 20460**

**OFFICE OF**
**PREVENTION, PESTICIDES AND**
**TOXIC SUBSTANCES**
**Antimicrobial Division**

06/16/06

| | | | |
|---|---|---|---|
| DP BARCODE: | D322901 | | |
| MRID : | 465388-01C, 465388-02, 465388-09 | | |
| SUBJECT: | Stalosan F | | |
| REG. NO. OR FILE SYMBOL: | 75526-R | | |
| DOCUMENT TYPE: | Product Chemistry Review | | |
| Manufacturing-use [] OR | End-use Product [X] | | |
| INGREDIENTS (PC Codes): | Copper sulfate pentahydrate (024401) | | |
| CAS Number: | (7758-99-8) | | |
| TEST LAB: | N/A | | |
| SUBMITTER: | ArchAngel LLC | | |
| GUIDELINE: | | | |
| COMMODITIES: | Formulation | | |
| REVIEWER: | Juan F. Negrón | ORGANIZATION: | AD |
| APPROVER: | Karen P. Hicks | APPROVED DATE: | 6/22/06 |
| COMMENT: | | | |

| | |
|---|---|
| **TO:** | Marshall Swindell / Martha Terry<br>PM Team 33 |
| **FROM:** | Juan F. Negrón, Chemist<br>Product Science Branch, CT Team<br>Antimicrobial Division (7510C) |
| **THRU::** | Karen P. Hicks, CT Team Leader<br>Product Science Branch<br>Antimicrobial Division (7510C) |
| **THRU:** | Michele E. Wingfield, Chief<br>Product Science Branch<br>Antimicrobial Division (7510C) |
| **APPLICANT:** | ArchAngel LLC |



**Action code:** A46
**Due date:** 08/20/06

**Product Formulation**
**Active Ingredient(s)**

| | **% by wt.** |
|---|---|
| Copper sulfate pentahydrate | 2.66 |

**BACKGROUND:**

The registrant, ArchAngel LLC, is submitting a new registration data package for review. The product is an integrated end-use product, Stalosan F, for non-health that controls, inhibits odor causing bacteria, fungi, mold, and mildew, and inhibits the growth of bacteria, & fungicide.

**FINDINGS:**

1. The Product Chemistry Reviewer has received the following documents:
   - Confidential Statement of Formula (CSF), dated 04/15/05, for the basic formulation.
   - A letter, dated 04/20/05.
   - A label, dated 05/02/05 (pin punch).
   - Application for pesticide, dated 04/20/05.
   - EPA meeting notes, dated 10/12/04.
   - Study titled "Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, and Density/relative Density." MRID # 465388-02.
   - Study titled "Accelerated Storage Stability Study." MRID # 465388-09.
   - Study titled "Product Identity and Composition, Beginning Materials, Production Process, Formation of Impurities, Preliminary Analysis, Certified Limits, and Analytical Method. MRID #465388-01C.
   - Pesticide Chemical Code (PCC) request form, dated 06/14/06. Revised 04/14/06.

2. The CSF, dated 04/15/05, for the basic formulation is revised.

3. The CSF and the label have the same nominal.

4. The inert, [redacted] as been cleared by the Agency.

5. The CAS number, [redacted] differs from the Agency (CAS # [redacted]).

6. The accelerated storage stability study was conducted for 28 day at 50 °C. The results of the assay show that the active ingredient (AI) meets EPA standard certified limits. The equation to calculate the percentage by weight of the AI does not indicate the instrument response values.

7. The Agency waives 830.6317 Storage Stability of the Product and 830.6320 Corrosion Characteristics guidelines. The product is a chemical commonly used, and the components are also well known.

8. The enforcement analytical method, 465388-01C, does not provide a detailed procedure to conduct a chemical analysis including the calculation to obtain the percentage by weight of the AI.

**RECOMMENDATIONS:**

1. The registrant should indicate the CAS number status in finding #5.

2. The registrant needs to submit an enforcement analytical method (830.1800 guideline) with a complete detail including the equation to calculate the percentage by weight of the AI.

3. The registrant needs to submit information for those 830 Gourp B guidelines that shows "G" (G means gap). These guidelines are required for all end-use products.

**CONCLUSION:**

The Confidential Statement of Formula (CSF), dated 04/15/06, for the basic formulation is acceptable. The enforcement analytical method stated in MRID #465388-01C is not acceptable. The registrant must comply with the requirements, recommendations and findings listed above.

## PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

| | | |
|---|---|---|
| | Non-integrated formulation system | [] |
| | Are all TGAIs used registered? | Yes [ ] No [ ] |
| X | Integrated formulation system | [X] |

If AME-TOO@, specify EPA Reg. # of existing product:

4b. Clearance of inerts for non-food or food use:
Cleared for food use under 40 CFR ' 180.1001: Yes [X] No [] NA []

4c. Physical state of product: *Solid*

4d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830, Group B:
Yes [X] No []

4e. NCs and CLs are acceptable: Yes [X] No []

| 4f. Active ingredient(s) | NC (%) | UCL (%) | LCL (%) |
|---|---|---|---|
| A. Copper sulfate pentahydrate | 2.66 | 2.79 | 2.53 |

4g. For products produced by an integrated formulation system:

All impurities of toxicological significance have a UCL?
Yes [ ] No [ ] Not applicable [X]

All impurities of $\geq$ 0.1% in the product have been identified?
Yes [ ] No [] Not applicable [X]

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC] is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [X] No [ ]

5b. The formulation contains one of the following:

| | | |
|---|---|---|
| a) 10% or more of a petroleum distillate: | Yes [ ] | No [X] |
| b) 1.0% or more of methyl alcohol: | Yes [ ] | No [X] |
| c) Sodium nitrite at any level: | Yes [ ] | No [X] |
| d) a toxic List 1 inert at any level: | Yes [ ] | No [X] |
| e) arsenic in any form: | Yes [ ] | No [X] |

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [ ] No [ ] Not applicable [X]

5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses?
PR Notice 84-1 Yes [] No [] Not applicable []
PR Notice 83-3 Yes [] No [] Not applicable []

5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?
Yes [ ] No [x] Pending []

**Product Chemistry (830 Series, Group A)**

| 6a. Data Requirements | Acceptance of Information | MRID No. |
|---|---|---|
| 830.1550[1] Product Identity | A | 465388-01C |
| 830.1600 Description of Materials | A | 465388-01C |
| 830.1620 Production Method[2] | A | 465388-01C |
| 830.1650 Formulation process[3] | A | 465388-01C |
| 830.1670 Formation of impurities[4] | A | 465388-01C |
| 830.1700 Preliminary Analysis[5] | A | 465388-01C |
| 830.1750 Certified Limits[6] | A | 465388-01C |
| 830.1800 Analytical Method[7] *Silver by Potentiometric Titration* | N | 465388-01C |

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), etc.

## Physical and Chemical Characteristics (Series 830, Group B)

| 6b. Physical/Chemical Properties* | Acceptance of data | Value or qualitative description | MRID No. |
|---|---|---|---|
| 830.6302 Color | A | Pinkish | 465388-02 |
| 830.6303 Physical State | A | Solid, powder | 465388-02 |
| 830.6304 Odor | A | Slightly sour | 465388-02 |
| 830.6313 Stability to Normal and Elevated Temperatures, Metals and Metal Ions | NA | | |
| 830.6314Oxidation/Reduction; chemical incompatibility | A | Compatible | 465388-02 |
| 830.6315 Flammability/Flame Extension | G | | |
| 830.6316 Explodability | G | | |
| 830.6317 Storage Stability | W | Accelerated storage stability (28days) study. | 465388-09 |
| 830.6319 Miscibility[2] | NA | | |
| 830.6320 Corrosion Characteristics | W | | |
| 830.6321 Dielectric Breakdown Voltage | G | | |
| 830.7000 pH | A | 4.62 ± 0.01 | 465388-02 |
| 830.7050 UV/ Visible absorption | NA | | |
| 830.7100 Viscosity | | | |
| 830.7200 Melting Point/Melting Range | NA | | |
| 830.7220 Boiling Point/Boiling Range | NA | | |
| 830.7300 Density/Relative Density/Bulk Density | A | Pour density 0.683 g/ml ± 0.002 | 465388-02 |
| 830.7370 Dissociation Constants in Water | NA | | |
| 830.7520 Particle size, diameter distribution | NA | | |
| 830.7550 Partition coefficient, (n-Octanol/Water shake flask method) | NA | | |
| 830.7560 Partition coefficient, (n-Octanol/Water generator column method) | NA | | |
| 830.7570 Partition coefficient, (n-Octanol/Water by liquid chromatography) | NA | | |
| 830.7840 Water Solubility: Column elution; shake flask method | NA | | |
| 830.7860 Water Solubility: Generator column method | NA | | |
| 830.7950 Vapor Pressure | NA | | |

Explanation: A=acceptable; N–not acceptable; NA=technically not applicable; G=data gap; U–requires upgrading; W–waived; E=EPA estimate; * Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc;
Unless otherwise indicated, the property should be at 25EC; [1] If product is dispersible with water; [2] If product is an emulsifiable liquid.

# CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC)
## REQUEST FORM
CR# 06-0274

| REQUESTOR NAME: **Juan F. Negrón** | | | Request date: **06/14/06** |
|---|---|---|---|
| Tel: **703-308-8116** | ORG.: **AD** | ROOM: **S-8848** | MAIL CODE: **7510P** |

CSF ATTACHED:
[x] YES If CSF is attached complete Item A and the chemical name in item C.
[ ] NO If CSF is not attached complete Item A through C.

**A. INFORMATION REQUIRED:**

*% Check Applicable Category*

[ ] Provide PCC and Tolerance Exemption Status For Food-Use inert ingredient (s).
[x] Provide PCC for Non-Food Use inert Ingredient (s).
[ ] Provide PCC for Active Ingredient (s).
[ ] Provide PCC for Dye.
[ ] Determine if Fragrance is Acceptable for Use In Formulation.
[ ] *Other (Describe):*_____

**B. PESTICIDE PRODUCT INFORMATION:**

| EPA Reg. No/File Symbol: **75525-R** | Product Name: **Stalosan F** |
|---|---|
| Registrant: **ArchAngel LLC** | Food-Use Pesticide: [ ] Yes [x] No |
| Percent in Formulation (For Fragrance /Dyes ) | |

**C. INGREDIENT INFORMATION:**

Ingredient No.1

**INFORMATION REPORTED:**

| Chem. Name: [redacted] | PCC: [redacted] |
|---|---|
| Synonym: [redacted] [redacted] | TOL. STATUS: |
| CAS Reg. No.: | OTHER INF.: NON-FOOD USE |

Ingredient No.2:

| Chem. Name: | PCC: |
|---|---|
| Trade Name: | TOL. STATUS: |
| CAS Reg. No.: | OTHER INF.: |

Ingredient No.3

| Chem. Name: | PCC: |
|---|---|
| Trade Name: | TOL. STATUS: |
| CAS Reg. No.: | OTHER INF.: |

Ingredient No.4:

| Chem. Name: | PCC: |
|---|---|
| Trade Name: | TOL. STATUS: |
| CAS Reg. No.: | OTHER INF.: |

Completed By: Alganesh Debesai
Date Completed: 6/14/06

*Inert ingredient information may be entitled to confidential treatment*

Decision #: 356769

# DATA PACKAGE BEAN SHEET

DP #: (322903)

Date: 26-Oct-2005



## * * * Registration Information * * *

**Registration:** 75526-R - STALOSAN F

Company: 75526 - ARCHANGEL LLC

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# CM-2 308H

Risk Manager Reviewer: Martha Terry MTERRY

Sent Date: _____ Calculated Due Date: 20-Aug-2006 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A46) NEW USE;WITH EXEMPTION;NEW FOOD USE;

Ingredients: 024401, Copper sulfate pentahydrate(2.66%)

## * * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 26-Oct-2005 Due Back: _____

DP Ingredient: 024401, Copper sulfate pentahydrate

DP Title: Acute Tox Data to support a new application

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #: _____

| | Assigned To | Date In | Date Out | |
|---|---|---|---|---|
| Organization: | AD / PSB | 10/27/05 | | Last Possible Science Due Date: 07-Apr-2006 |
| Team Name: | CTT | 10/27/05 | | Science Due Date: 7/20/06 |
| Reviewer Name: | Dan Wallace | 11/10/05 | | Sub Data Package Due Date: 7/6/06 |
| Contractor Name: | | | | |

## * * * Studies Sent for Review * * *

No Studies

## * * * Additional Data Package for this Decision * * *

Printed on Page 2

## * * * Data Package Instructions * * *

Please review the acute toxicity data submitted in support of this application. The MRID#s are: 46538803, -04, -05-, -06, -07, -08. A proposed label, and a CSF are also included.

This application is being reviewed in conjunction with a Tolerance Exemption Petition 5F6982 for use in livestock premises.

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 13, 2006

MEMORANDUM

Subject: Data Package D322903
Stalosan F, EPA File Symbol 75526-R

From: Wallace Powell, Biologist
Product Science Branch
Antimicrobials Division (7510P)

6/13/06

Through: Karen P. Hicks, Team Leader
Chemistry/Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

6/13/06

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell, Product Manager, Team 33
Martha Terry, Team Reviewer, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

BACKGROUND

The applicant, ArchAngel LLC, has submitted studies for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary skin irritation, and skin sensitization – MRIDs 46538803 through 46538808, respectively. Reviews of the studies are attached to this memorandum. The studies were submitted in support of Stalosan F, an adsorbent for use in livestock housing. The product is labeled with the sole active ingredient copper sulfate pentahydrate, 2.66% by weight.

RECOMMENDATION

The submitted studies are acceptable. The test material identified in the study reports apparently represents the subject product. The resulting acute toxicity regulatory profile for Stalosan F is as follows:

| | | | |
|---|---|---|---|
| 870.1100 | Acute oral toxicity | MRID 46538803, submitted | Acceptable, Tox Category IV |
| 870.1200 | Acute dermal tox. | MRID 46538804, submitted | Acceptable, Tox Category IV |
| 870.1300 | Acute inhalation tox. | MRID 46538805, submitted | Acceptable, Tox Category IV |
| 870.2400 | Eye irritation | MRID 46538806, submitted | Acceptable, Tox Category III |
| 870.2500 | Skin irritation | MRID 46538807, submitted | Acceptable, Tox Category IV |
| 870.2600 | Skin sensitization | MRID 46538808, submitted | Acceptable, Non-sensitizer |

Product labeling

The first-aid and human-hazard precautionary statements in the proposed label (EPA Received date 5/2/2005) are acceptable.

**DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OPPTS 870.1100)**

**Product Manager**: Marshall Swindell
**MRID No.**: 46538803

**Reviewer**: W. Powell 6/13/2006
**DP Barcode**: D322903

**Study Completion Date**: 3/10/2005
**Report/Study No.**: 16447

**Testing Laboratory:** Product Safety Laboratories – Dayton, New Jersey

**Author**: Daniel J. Merkel

**GLP Compliance Statement (40 CFR §160.12)**: Included

**Test Material**: Stalosan F, a pinkish powder
**Dosage**: 5 g per kg body weight, dosed as 40% w/w in distilled water

**Species**: Rat, Sprague-Dawley derived (3 females)
**Weight**: 189-209 g
**Age**: 11-12 weeks at start of testing
**Source**: Ace Animals, Inc., Boyertown, PA

**Summary**:

1. **$LD_{50}$**: >5000 mg/kg (females)
2. **Tox. Category**: IV
3. **Classification**: Acceptable

**Procedure (Deviations from Guidelines)**:
No deviations from Guidelines were noted.

**Results**:

The study was conducted as a limit test by the Up-And-Down Method. Each animal survived, gained weight, and appeared active and healthy during the 14-day observation period. Clinical and post-mortem findings were unremarkable. The $LD_{50}$ was greater than 5000 mg/kg in female rats. The results place the test substance in acute oral toxicity Category IV.

**DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OPPTS 870.1200)**

**Product Manager**: Marshall Swindell
**MRID No.**: 46538804

**Reviewer**: W. Powell 6/13/2006
**DP Barcode**: D322903

**Study Completion Date**: 3/10/2005
**Report/Study No.**: 16448

**Testing Laboratory:** Product Safety Laboratories – Dayton, New Jersey

**Author**: Daniel J. Merkel

**GLP Compliance Statement (40 CFR §160.12)**: Included

**Test Material**: Stalosan F, a pinkish powder
**Dosage**: 5 g per kg body weight, applied as a dry paste 60% w/w in distilled water

**Species**: Rat, Sprague-Dawley derived (5 per sex)
**Weight**: Males 344-360 g, Females 212-224 g
**Age**: 10-11 weeks
**Source**: Ace Animals, Inc., Boyertown, PA

**Summary**:

1. **$LD_{50}$** (males, females, combined): >5000 mg/kg
2. **Tox. Category**: IV
3. **Classification**: Acceptable

**Procedure (Deviations from Guidelines)**:
Relative Humidity was not listed in the study report. This should not affect the study outcome. No other deviations from Guidelines were noted.

**Results**:

All animals survived the observation period. Acute dermal toxicity Category IV is indicated based on the limit test.

| Dosage (mg/kg) | Reported Mortality (Number Deaths/Number Tested) | | |
|---|---|---|---|
| | Males | Females | Combined |
| 5000 | 0/5 | 0/5 | 0/10 |

**Observations**:

Each animal survived, gained weight, and appeared active and healthy during the 14-day observation period. Clinical and post-mortem findings were unremarkable.

**DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OPPTS 870.1300)**

**Product Manager**: Marshall Swindell
**MRID No.**: 46538805

**Reviewer**: W. Powell 6/13/2006
**DP Barcode**: D322903

**Study Completion Date**: 3/10/2005
**Report/Study No.**: 16449

**Testing Laboratory**: Product Safety Laboratories – Dayton, New Jersey

**Author**: Daniel J. Merkel

**GLP Compliance Statement (40 CFR §160.12)**: Included

**Test Material**: Stalosan F, a pinkish powder
**Dosage concentration**: 2.07 mg/L

**Species**: Rat, Sprague-Dawley derived (5 per sex)
**Weight**: Males: 223-245 g, Females 176-200 g
**Age**: 8-9 weeks
**Source**: Ace Animals, Inc., Boyertown, PA

**Summary**:

1. **$LC_{50}$** (Males, Females, Combined): >2.07 mg/L
2. **MMAD**: 2.8 µm
3. **Tox. Category**: IV
4. **Classification**: Acceptable

**Procedure**:

No deviations from Guidelines were noted.

Test material was prepared by milling and was applied to nose-only exposure chamber by a dust generator. Mass median aerodynamic diameter (MMAD) was based on graphic analysis of particle size distribution as measured with a cascade impactor for two samples taken at suitable times during the exposure period. Exposure was 4 hours plus 1 minute for 99% atmosphere equilibration. Chamber concentration was measured gravimetrically based on samples taken at 6 intervals from the breathing zone.

**Results**:

All animals (5 per sex) survived the 14-day observation period following a 4-hour exposure to a test atmosphere at a concentration of 2.07 mg/L. Acute inhalation toxicity Category IV is therefore indicated based on the limit test.

In-chamber and post-exposure clinical signs during the 14-day observation period: none noted. All animals gained body weight and appeared active and healthy during the observation period. Necropsy signs: no gross abnormalities.

Exposure period data are indicated in the following tables.

**Chamber Atmosphere** (averages)

| Exposure Concentration (mg/L) | MMAD (µm) | GSD (µm) | % Particles <1.1 µm | % Particles <4.7 µm |
|---|---|---|---|---|
| 2.07 mg/L | 2.8 | 2.04 | 10.0 | 77.8 |

**Chamber Environment**

| | |
|---|---|
| Chamber Volume | 6.7 L |
| Airflow | 31.6 to 31.9 Lpm |
| Temperature | 21 to 22 °C |
| Relative Humidity | 41 to 48 % |

**DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)**

**Product Manager**: Marshall Swindell
**MRID No.**: 46538806
**Reviewer**: W. Powell 6/13/2006
**DP Barcode**: D322903

**Study Completion Date**: 3/10/2005
**Report/Study No.**: 16450

**Testing Laboratory:** Product Safety Laboratories – Dayton, New Jersey

**Author**: Daniel J. Merkel

**GLP Compliance Statement (40 CFR §160.12)**: Included

**Test Material**: Stalosan F, a pinkish powder. Prepared for dosing by grinding.
**Dosage**: 0.1 mL

**Species**: Rabbit, New Zealand albino (3 males)
**Weight**: Not Indicated
**Age**: Young adult (not further specified)
**Source**: Robinson Services, Inc., Clemmons, NC

**Summary**:

1. **Tox. Category**: III
2. **Classification**: Acceptable

**Procedure (Deviations from Guidelines)**: No deviations noted

**Results**:

No corneal opacity was observed. Mild iridal involvement, grade 1 on the Draize scale, was observed in 3/3 animals at 1 hour, clearing in all animals by 24 hours. Moderate conjunctival redness, grade 2 on the Draize scale, was observed in 3/3 animals 1 hour post-instillation and persisted in 2/3 animals through 48 hours. 'Positive' degree of conjunctival redness cleared in all animals by 72 hours. No conjunctival swelling (chemosis) was observed. The study results place the test material in Category III for eye irritation. The test material can be considered a mild eye irritant in the study.

| Observations | Number 'Positive'/Number Tested | | | |
|---|---|---|---|---|
| | Hour | | | |
| | 1 | 24 | 48 | 72 |
| Cornea | 0/3 | 0/3 | 0/3 | 0/3 |
| Iris | 3/3 | 0/3 | 0/3 | 0/3 |
| Conjunctivae: | | | | |
| Redness | 3/3 | 2/3 | 2/3 | 0/3 |
| Chemosis | 0/3 | 0/3 | 0/3 | 0/3 |

## DATA REVIEW FOR ACUTE SKIN IRRITATION TESTING (OPPTS 870.2500)

**Product Manager**: Marshall Swindell
**MRID No.**: 46538807

**Reviewer**: W. Powell 6/13/2006
**DP Barcode**: D322903

**Study Completion Date**: 3/10/2005
**Report/Study No.**: 16451

**Testing Laboratory:** Product Safety Laboratories – Dayton, New Jersey

**Author**: Daniel J. Merkel

**GLP Compliance Statement (40 CFR §160.12)**: Included

**Test Material**: Stalosan F, a pinkish powder. Applied as a paste, mixed 60% w/w with distilled water
**Dosage**: 0.5 g

**Species**: Rabbit, New Zealand albino (2 males, 1 female)
**Weight**: Not specified
**Age**: Young adult (not further specified)
**Source**: Robinson Services, Inc., Clemmons, NC

**Summary**:

1. **Tox. Category**: IV
2. **Classification**: Acceptable

**Procedure (Deviations from Guidelines)**: No deviations noted

**Results**:

No erythema or edema was observed. All animals appeared active and healthy during the study. The results place the test material in Tox Category IV for skin irritation. The test material can be considered non-irritating in this study.

**DATA REVIEW FOR DERMAL SENSITIZATION TESTING (OPPTS 870.2600)**

**Product Manager**: Marshall Swindell
**MRID No.**: 46538808
**Reviewer**: W. Powell 6/13/2006
**DP Barcode**: D322903

**Study Completion Date**: 3/10/2005
**Report/Study No.**: 16452

**Testing Laboratory:** Product Safety Laboratories (PSL) – Dayton, New Jersey

**Author**: Daniel J. Merkel

**GLP Compliance Statement (40 CFR §160.12)**: Included

**Test Material**: Stalosan F, a pinkish powder. Ground and applied as 0.4 g of a 65% w/w mixture in mineral oil for induction, 0.4 ml of 33% w/w in mineral oil for challenge.
**Positive Control Material**: alpha-hexylcinnamaldehyde technical grade for induction, 75% w/w in mineral oil for challenge

**Species**: Guinea pig, Hartley albino
**Number**: 4 (males) in preliminary irritation screening for main study;
20 (females) in Test group of main study;
10 (males and females) in Test group of positive control study;
10 (females) in Naive Control group of main study;
5 (males and females) in Naive Control group of positive control study
**Age and Weight**:
Animals in main study: young adults.
Animals in Test and Naive Control groups of main study:
380-447 grams initial weight.
Animals in positive control study: 441-587 grams, age not stated
**Source**: Elm Hill Breeding Labs – Chelmsford, MA

**Method**: Buehler

**Summary**:

1. **Outcome**: Test material was not a dermal sensitizer.
2. **Classification**: Acceptable

**Procedure (Deviations from Guidelines):**

Although no screening data were given to support the selection of the challenge concentration in the historical positive control study, the naive control data may be considered sufficient in this study.

In the definitive (main, not positive control) study, induction concentration at first glance would appear insufficient based on low erythema response. However, this appears to have been unavoidable. According to the study report, "Preliminary solubility testing conducted by PSL indicated that concentrations in excess of 65% were too dry to allow for adequate contact with the skin."

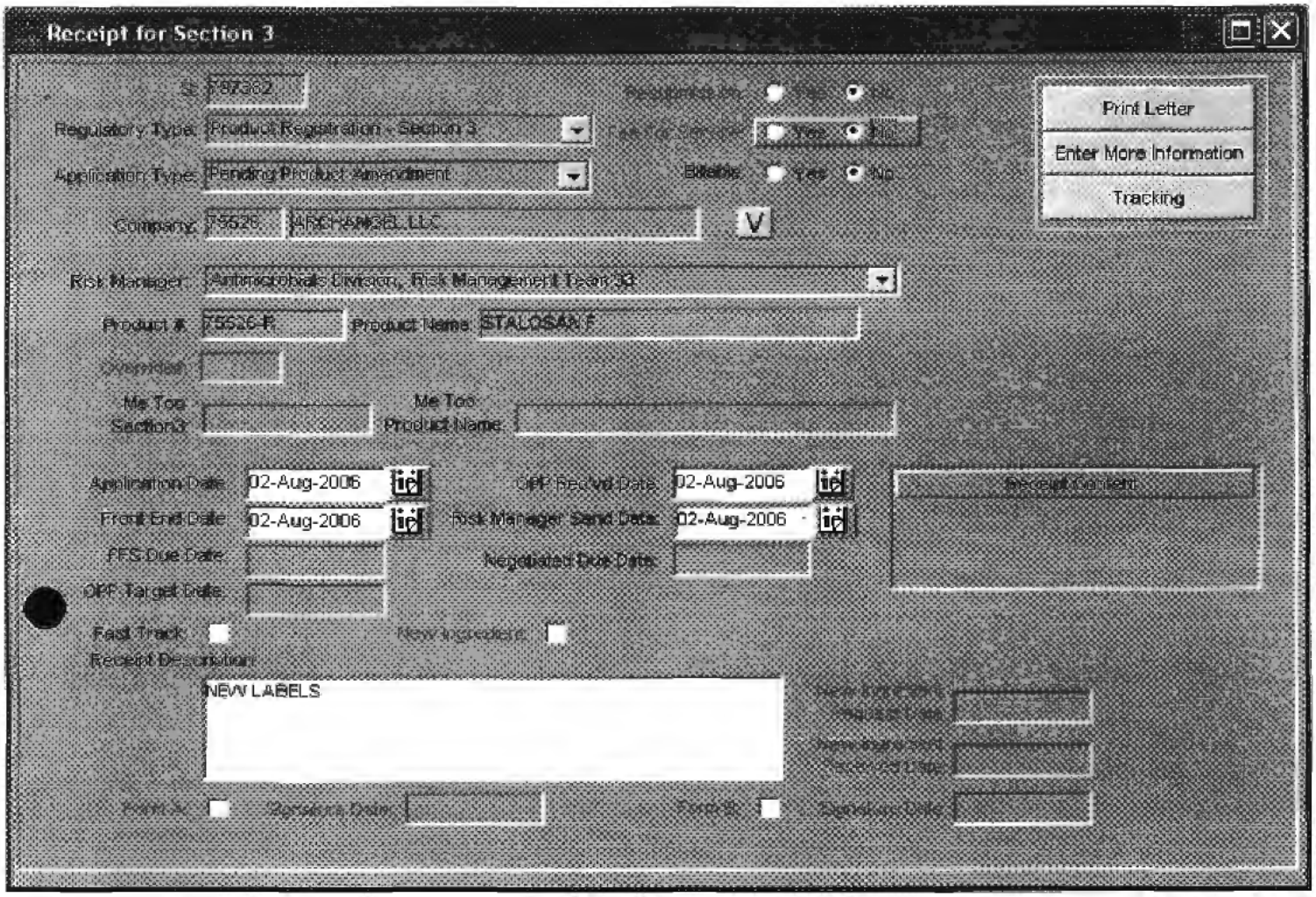
***Results***:

In the main study, erythema response to challenge was similar between test group and naive control group. Thus, the test substance did not elicit contact hypersensitivity.

In the positive control study, erythema response to challenge was significantly greater in the test group than in the naive control group. Thus, the positive control data requirement is fulfilled.

The dosing concentrations selected for test substance and positive control substance appear appropriate.

Positive control study was conducted within 6 months of main study, as required.


Receipt for Section 3
Print Letter
Enter More Information
Tracking
Regulatory Type: Product Registration - Section 3
Application Type: Pending Product Amendment
Company: 75526 ARCH CHEMICALS, LLC
Risk Manager: Antimicrobials Division, Risk Management Team 33
Product #: 75526-R
Product Name: STALOSAN F
Override:
Me Too Section 3:
Me Too Product Name:
Application Date: 02-Aug-2006
Front End Date: 02-Aug-2006
FFS Due Date:
OPP Target Date:
OPP Rec'vd Date: 02-Aug-2006
Risk Manager Send Date: 02-Aug-2006
Negotiated Due Date:
Receipt Content:
Fast Track:
New Ingredient:
Receipt Description:
NEW LABELS
Form 3:
Signature Date:
Form 8:

**Robert Brennis**
**<bbrennis@lewisharrison.com>**
08/02/2006 05:27 PM

To Martha Terry/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA
cc "Kent Adams (E-mail)" <kentadams@adams.net>
bcc
Subject Revised label

Martha and Marshall -

Thank you for the call you made to me this morning and clarifying issues with the label. I have made all of the changes you had indicated and have attached the label to this email for your review. We moved the Ingredient Statement over the Signal Word, we changed any reference to bacteria or fungi inhibition to non public health, and most significantly, we identified the specific methods of application for this product and added appropriate wording.

I appreciate your efforts and hope to obtain the registration soon. If you are going to issue the registration, please call me so that I can pick it up or obtain it quickly.

Bob

Robert S. Brennis
Lewis & Harrison
122 C St. NW, Suite 740
Washington, DC 20001
Phone: 202-393-3903 ext. 20
Fax: 202-393-3906

Stalosan F label Aug2.doc

D. Edwards (7510)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 11 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

***Product ingredient source information may be entitled to confidential treatment***

The Honorable James M. Talent
United States Senator
Three City Place Drive, Suite 1020
St. Louis, MO 63141

Dear Senator Talent:

Thank you for your December 12, 2005, letter on behalf of your constituent, Jesse Heimer of ArchAngel, LLC. Mr. Heimer has asked for assistance in getting his company's product, Stalosan F, registered in the United States with EPA. Currently, this product is produced by a [redacted] and is marketed in Europe as an odor abatement product for livestock. We appreciate Mr. Heimer's concerns and are working to assist him in the registration of this product.

There are several key areas I would like to address in Mr. Heimer's letter. Mr. Heimer has expressed concerns that his company has invested three years and considerable resources in its efforts to register Stalosan F in the United States. As is customary for anyone seeking an EPA registration, we held pre-registration meetings with ArchAngel, LLC to inform them of the registration requirements as they apply to this product. Subsequent to these meetings, ArchAngel submitted its initial registration application on April 20, 2005. Unfortunately, the application did not include data to support a tolerance exemption, and we were not able to process the application. A tolerance exemption is necessary because the product will be used in facilities where animals are present, and there could be product residues in the meat or meat by-products. We informed ArchAngel of this requirement and asked the company to submit a tolerance exemption petition, which we received on August 10, 2005.

Additionally, Mr. Heimer noted the product should not be subjected to the same efficacy tests as liquid disinfectants. This efficacy data must be submitted to EPA with the application for registration only for products making public health claims. We are not requiring submission of efficacy data to support the proposed uses of Stalosan F because, as proposed for use in the United States, Stalosan F would be produced as an antimicrobial microbiocide for use in livestock odor abatement in confined spaces (e.g., barns, stables), which is not a public health claim. However, regardless of the physical form of the product, if public health or marketing claims were to be submitted to EPA on the product label for Stalosan F, then performance data that meet our current efficacy requirements would be required. All applicants are required to develop data to support the claims made on the product label.

As you know, in January 2003, the Pesticide Registration Improvement Act (PRIA) was enacted. This law established a fee structure and timelines for Agency review of applications for registration. Under PRIA, the due date for an Agency determination on the Stalosan F application is August 2006. At this time, the Agency is reviewing the data submitted to support the Stalosan F application. Barring any unforeseen issues, the Agency expects to make a final determination on the Stalosan F application in spring of 2006, well in advance of the PRIA due date.

Again, thank you for your letter and for bringing this matter to my attention. I hope that this information will prove to be helpful to you and Mr. Heimer. If you have any further questions, please contact me, or your staff may contact Betsy Henry in our Office of Congressional and Intergovernmental Relations at 202-564-7222.

Sincerely,

Susan B. Hazen
Principal Deputy Assistant Administrator

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

7506C/OPP/FEAD/CSB/R. Jackson/308-2952/December 22, 2005
V:\PSPS\Lets2005\
bcc: TS AL HOLD(7506C) Susan Laing (7510C) Martha Terry (7510C) Marshall Swindell (7510C) Dennis Edwards (7510C)

***Product ingredient source information may be entitled to confidential treatment***

The Honorable James M. Talent
United States Senator
Three City Place Drive
Suite 1020
St. Louis, MO 63141

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Additionally, Mr. Heimer noted the product should not be subjected to the same efficacy tests as liquid disinfectants. All applicants are required to develop data to support the claims made on the product label. We are not requiring submission of efficacy data to support the proposed uses of this product because, as proposed for use in the United States, Stalosan F would be produced in granular form as an antimicrobial microbiocide for use in livestock odor abatement in confined spaces (e.g., barns, stables), which is not a public health claim. These data must be submitted to EPA at the time of application for registration only for products making public health claims. Further, regardless of the physical form of the product, if public health label or marketing claims were to be submitted to EPA, then performance data that meet our current efficacy requirements would be required.

| CONCURRENCES | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| SYMBOL | 7506C | 7510C | 7510C | FEAD | 7501-C | OPPTS | | |
| SURNAME | Keas for Rand | Laing | Sheridan | Moos | Mitchell | Schmidt | | |
| DATE | 12/22/05 | 12/22/05 | 12/22/05 | 12/22 | 12/23/05 | 12/24/05 | | |

EPA Form 1320-1A (1/90) *Printed on Recycled Paper* OFFICIAL FILE COPY

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Again, thank you for your letter and for bringing this matter to my attention. I hope that this information will prove to be helpful to you and Mr. Heimer. If you have any further questions, please let me know or your staff may contact Betsy Henry in our Office of Congressional and Intergovernmental Relations at 202-564-7222.

Sincerely yours,

Susan B. Hazen
Principal Deputy Assistant Administrator

# Correspondence Management System

## Tracking Document

Due date: 12/29/05

**Control No.:** AL-05-001-8847
**Status:** Pending
**Due Date:** Jan 04, 2006
**Letter Date:** Dec 12, 2005
**Received Date:** Dec 21, 2005
**Close Date:** N/A
**# of Extensions:** 0
**Notes:**
**Alt No.:**
**File Code:** 141-A CONGRESSIONAL CORRESPONDENCE
**From:** James Talent
Organization: United States Senate
Street: SR-493 Russell Senate Office Building
City/State/Zip: Washington / DC / 20510
Country: USA
**Committee:**
**Sub Committee:**
**Constituent:** JESSE HEIMER
**To:**
**To Org:**
**Subject:** REQUEST A WRITTEN REPORT ON THE CURRENT STATUS OF THE APPLICATION ON THE REGISTRATION OF STALOSAN F
**Signature:** AA-OPPTS-Assistant Administrator - OPPTS
**Signature Date:** N/A
**Instruction Codes:** AA-OPPTS-Prepare draft response for signature by the Assistant Administrator for OPPTS
**Instruction Notes:**
**Lead Author:**
**Lead Author Office:**
**Lead Author Due Date:** N/A
**Lead Author Assigned Date:** N/A
**Lead Author Complete Date:** N/A
**Lead Author Instruction:**
**Supporting Author:**
**CC:** BETSY HENRY, Region 7

**Lead Info:**

| Assigner | Office | Assignee | Assigned Date | Due Date | Instructions | Completed Date |
|---|---|---|---|---|---|---|
| Cassaundra Eades | OCIR | OPPTS | Dec 21, 2005 | Jan 04, 2006 | AA-OPPTS-Prepare draft response for signature by the Assistant Administrator for OPPTS | N/A |
| Zelma Taylor | OPPTS | OPPTS-OPP | Dec 21, 2005 | Dec 30, 2005 | Prepare draft response for AA/ OPPTS Signature | N/A |

## Support Info:

| Assigner | Office | Supporting Assignee | Assigned Date |
|---|---|---|---|
| No records found | | | |

## Assignment History:

| Assigner | Office | Action | Date of Action |
|---|---|---|---|
| Cassaundra Eades | OCIR | Assign OPPTS as lead office | Dec 21, 2005 |
| Zelma Taylor | OPPTS | Assign OPPTS-OPP as lead office | Dec 21, 2005 |

## Assignment Comments:

| Commentator | Comment | Date of Comment |
|---|---|---|
| No records found | | |

JAMES M. TALENT
MISSOURI
http://talent.senate.gov

CHAIRMAN
SUBCOMMITTEE ON SEAPOWER
CHAIRMAN
SUBCOMMITTEE ON MARKETING, INSPECTION AND PRODUCT PROMOTION

DEPUTY MAJORITY WHIP

# United States Senate

493 RUSSELL SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224-6154
FAX (202) 228-1518

COMMITTEES
ARMED SERVICES
AGRICULTURE, NUTRITION AND FORESTRY
ENERGY AND NATURAL RESOURCES
SPECIAL COMMITTEE ON AGING

December 12, 2005

Mr. Charles L. Engebretsen
Associate Administrator of Congressional and Intergovernmental Affairs
Environmental Protection Agency
1200 Pennsylvania Avenue, Northwest
Room 3428 ARN
Washington, D.C. 20460

Dear Mr. Engebretsen:

I am writing to you on behalf of my constituent, Jesse Heimer, and his company, ArchAngel, LLC, and am enclosing a copy of his letter to me regarding his company's desire to have Stalosan F, (Environmental Protection Agency (EPA) application number: 75526-R) approved by your agency.

Mr. Heimer has told me that after a meeting with EPA officials in October 2004, his company complied with all recommendations, developed the necessary data and submitted an application on April 20, 2005, requesting acceptance of this registration request. Mr. Heimier went on to state that this was no small feat for a small business such as his company.

Under the circumstances, I would be most grateful if you would review my constituent's file and furnish me a written report on the current status of his company's application. Furthermore, I would appreciate your extending all possible favorable and expeditious consideration to his application, consistent with your regulations, to the end that ArchAngel, LLC, may receive as soon as possible registration approval for Stalosan F.

Thank you for your cooperation and assistance, and I will wait receiving your written reply on behalf of my constituent in the early future. Please respond to my St. Louis office which is located at Three City Place Drive, Suite 1020, St. Louis, Missouri 63141.

Sincerely,

James M. Talent
United States Senator

JMT/dd
Enclosure

THREE CITY PLACE DRIVE
SUITE 1020
ST. LOUIS, MO 63141
PHONE (314) 432-5211
FAX (314) 432-5894

1721 WEST ELEMDALE
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122 EAST HIGH STREET, 2ND FLOOR
JEFFERSON CITY, MO 65101
PHONE (573) 636-3070
FAX (573) 636-3891

WHITTAKER FEDERAL COURTHOUSE
400 EAST 9TH STREET
SUITE 40 PLAZA LEVEL
KANSAS CITY, MO 64106
PHONE (816) 421-1639
FAX (816) 421-2562

339 BROADWAY, ROOM 136
CAPE GIRARDEAU, MO 63701
PHONE (573) 651-0964
FAX (573) 334-4278

***Product ingredient source information may be entitled to confidential treatment***

**Arch Angel, LLC**
636 Hampshire St.
Quincy, IL 62301

2005 NOV -5 PM 1:52

Mrs. Katie Smith
Senior Legislative Assistant to Senator Jim Talent
493 Russell Building
Washington, D.C. 20510

Dear Katie:

It was a pleasure talking to you today about our Company; our products (including *Stalosan F™, the livestock odor abatement product*); current issues related to US registration of Stalosan F™; and other related matters. I'm sure the time we spent together will be useful in helping us to resolve our problems. My colleagues and I certainly look forward to working with you, Senator Talent, and any other persons who you believe can help our cause.

As mentioned, I indicated that I would formalize our telephone conversation by providing you a written description of our Company, the nature of Stalosan F™ (Material Specifications), the efficacy of Stalosan F™ (Effectiveness), and, as mentioned during the course of our telephone conversation, the current problems we have encountered in attempting to get our product registered with the EPA (Issues).

As you will see, there is no reason that this product should not be approved immediately by the EPA. It is with regard to this matter that we seek your immediate help.

Our Company:

Our Company is an Illinois-chartered Limited Liability Company named "ArchAngel, LLC." The primary mission of our Company is to market and sell safe, natural products that promote animal health (and, hence, human health). At this time, our product portfolio is limited to importing and marketing the superb livestock odor abatement / dry disinfectant product produced by [redacted] company that has marketed and sold natural animal-health and livestock odor abatement products for many decades. In fact, [redacted] is the odor abatement product 'company of choice' for literally thousands of European livestock producers and has been so for many, many years. Furthermore, ArchAngel, LLC and [redacted] have formalized a joint-agreement to manufacture Stalosan F™ in the United States, pending an EPA registration. The process has begun to secure a manufacturing site which would serve the Western Hemisphere and perhaps Asia.

Material Specifications of Stalosan F™:

Stalosan *F™ is a powder of small particle size which is a mixture of* [redacted]

***Inert ingredient information may be entitled to confidential treatment***

[redacted] All of the active ingredients in the product are inorganic powders except for the perfume agent. The production process for this product is proprietary and covered by various patents. The product is imported into the United States as 55-pound bags stacked on pallets and placed inside containers. Importantly, note that this odor abatement product has significant disinfectant and antimicrobial properties – properties that contribute significantly to both the health of livestock and, the people who work in livestock production facilities. Additionally, unlike other common disinfectants, the product is completely safe for use in the presence of animals and human labor at all stages of production.

Effectiveness:

As mentioned, Stalosan F™ has both antimicrobial properties and odor abatement properties. Stalosan F™ essentially eliminates all odors arising from raising livestock in confined spaces by accomplishing the following:

- Inhibiting the metabolism and proliferation of bacteria and fungus through the use of its highly-reactive copper compounds
- Inhibiting the reproduction of bacteria, viruses, parasites, and fly-larvae through the use of minerals (Moler earth) that bind to the surface of these pests (rendering them inactive during the reproductive phase of these pests' life-cycle)
- Killing parasites, fly-larvae, insects, and worms (of various types) through the use of the sharp-edged crystalline shape of the product that penetrates the surface of these pests
- Killing bacteria and other pests through the use of its acidic surface
- Chemically inactivating urease, the enzyme found in swine and poultry urine that creates ammonia. And, note that it is the horrific ammonia odor emanating from swine and poultry operations that gives rise to the thousands of complaints registered by citizens in many communities throughout the United States.

Note also that all of the aforementioned items are substantiated with a voluminous amount of test data that has been performed at the expense of [redacted] in an effort to get approval (which they have done) for marketing and selling this product in many countries in Europe and in other parts of the world. In fact, the quantity and quality of research testing performed by [redacted] overwhelming and is available for viewing by the general public at the Company's web-site at [redacted]

Issues:

We have spent the past three years and a substantial amount of money in an attempt to get Stalosan F™ approved by the EPA for use in the United States. Our goal is to claim that our product:

- Eliminates the majority of odors normally associated with the production of livestock (again, in confined spaces)
- Creates a healthier environment for livestock production areas over which the product is employed

As a result of these two beneficial attributes, our marketing literature will further elaborate that our product thus promotes improved animal health, improved and more sanitary meat products originating from livestock operations that employ our product, and, hence, promotes improved human health.

In the United States, the EPA registers disinfectants for use as liquids – not powders, as is the case with Stalosan F™. These liquid disinfectants are subjected to a standard test that requires, among other items, that the disinfectant kill all of a specific amount of a control pathogen in a specified period of time. Stalosan F™, being a powder, has no hope of working as fast as a liquid disinfectant. However, the product is more effective (kills more pathogens / works longer) than any known liquid disinfectant for its intended use. Moreover, it is a complex mixture of naturally occurring products that have, *individually or collectively, no deleterious effects on humans*, animals, or the environment. Specifically, none of the active ingredients in the product are – by EPA definitions – hazardous ingredients.

Our contentions are as follows:

- Stalosan F™ is a powder 'antimicrobial' (and odor abatement product) and should not be subjected to the same tests as are performed on liquid disinfectants.
- The EPA should grant Stalosan F™ an antimicrobial registration quickly.

It's unfortunate that the product was not developed in the United States and that the EPA does not have any viable tests for products such as ours. But, in this case (livestock odor abatement and related animal health), we Americans have something to learn from our European 'cousins.'

Please help us get this product through the maze and roadblocks that we are facing in Washington. I'm sure that your constituents will become the rightful beneficiaries of a community with less odors, healthier animals, healthier meat products, and, most importantly, healthier families. Stalosan F™ really does work and it is time for the American public to benefit from this product.

Regards,

Jesse Heimer
ArchAngel, LLC

## SCOPING MEETING - NOVEMBER 9, 2005

**Archangel LLC has submitted a new application on April 20, 2005 (Stalosan F, EPA File Symbol 75526-R) for the use of Copper Sulfate Pentahydrate in livestock housing to inhibit the growth of mold, mildew and odor causing bacteria on livestock floors.**

**Directions For Use:**

**Use 1 pound of material to 100 Sq. ft, 1 time per day for 3 days and continue use 1 time a week thereafter.**

**This is a new use pattern (code A46) for Copper Sulfate pentahydrate. A 100% waiver was granted on 5/27/05. The due date for this application is 8/20/06. The company was informed that this is a food use and would require a Tolerance Petition or an Exemption from tolerance.**

**A Tolerance Exemption has been granted for meat, poultry, milk, eggs, fish, shellfish and irrigated crops. A Tolerance Exemption Petition has been filed (5F6982) on 8/10/05, and no fee is required. The Petition due date is 12/06.**

**Science Data packages have been sent to RASSB for review including the CSF, label, 2 Tox. Studies, the Petition and an HED Tox Risk Assessment for Copper Sulfate Pentahydrate.**

**Questions:**

1. **Does RASSB see any major problems?**

2. **Is a full Risk Assessment required?**

Martha Terry (7510)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 29 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

The Honorable Charles E. Grassley
United States Senate
Washington, DC 20510

***Product ingredient source information may be entitled to confidential treatment***

Dear Senator Grassley:

Thank you for your October 26, 2005, letter on behalf of your constituent, Mr. Glen Gabriel of ArchAngel, LLC. Mr. Gabriel has asked for assistance in getting his company's product, Stalosan F, registered in the United States with EPA. Currently, this product is produced by a [redacted] and is marketed in Europe as an odor abatement product for livestock. We appreciate Mr. Gabriel's concerns and are working to assist him in the registration of this product.

There are several key areas I would like to address in Mr. Gabriel's letter. Mr. Gabriel has expressed concerns that his company has invested three years and considerable resources in its efforts to register Stalosan F in the United States. As is customary for anyone seeking an EPA registration, we held pre-registration meetings with ArchAngel, LLC to inform them of the registration requirements as they apply to this product. Subsequent to these meetings, ArchAngel submitted its initial registration application on April 20, 2005. Unfortunately, the application did not include data to support a tolerance exemption, and we were not able to process the application. A tolerance exemption is necessary because the product will be used in facilities where animals are present, and there could be product residues in the meat or meat by-products. We informed ArchAngel of this requirement and asked the company to submit a tolerance exemption petition, which we received on August 10, 2005.

Additionally, Mr. Gabriel noted the product should not be subjected to the same efficacy tests as liquid disinfectants. This efficacy data must be submitted to EPA with the application for registration only for products making public health claims. We are not requiring submission of efficacy data to support the proposed uses of Stalosan F because, as proposed for use in the United States, Stalosan F would be produced as an antimicrobial microbiocide for use in livestock odor abatement in confined spaces (e.g., barns, stables), which is not a public health claim. However, regardless of the physical form of the product, if public health or marketing claims were to be submitted to EPA on the product label for Stalosan F, then performance data that meet our current efficacy requirements would be required. All applicants are required to develop data to support the claims made on the product label.

As you know, in January 2003, the Pesticide Registration Improvement Act (PRIA) was enacted. This law established a fee structure and timelines for Agency review of applications for registration. Under PRIA, the due date for an Agency determination on the Stalosan F

application is August 2006. At this time, the Agency is reviewing the data submitted to support the Stalosan F application. Barring any unforeseen issues, the Agency expects to make a final determination on the Stalosan F application in Spring of 2006, well in advance of the PRIA due date.

Again, thank you for your letter and for bringing this matter to my attention. I hope that this information will prove to be helpful to you and Mr. Gabriel. Please contact me if you have further concerns, or your staff may contact Betsy Henry in our Office of Congressional and Intergovernmental Relations at 202-564-7222.

Sincerely yours,

Susan B. Hazen
Principal Deputy Assistant Administrator

***Product ingredient source information may be entitled to confidential treatment***

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

7506C/OPP/FEAD/CSB/R. Jackson/308-2952/November 29, 2005
V:\PSPS\Lets2005\AL-05-001-7416
bcc: TS AL HOLD(7506C) Susan Laing (7510C) Martha Terry (7510C)
Marshall Swindell (7510C) Dennis Edwards (7510C)

The Honorable Charles E. Grassley
United States Senate
Washington, DC 20510

Dear Senator Grassley:

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See revised scanned letter in CMS

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

***Product ingredient source information may be entitled to confidential treatment***

7506C/OPP/FEAD/CSB/R. Jackson/308-2952/November 29, 2005
V:\PSPS\Lets2005\AL-05-001-7416
bcc: TS AL HOLD(7506C) Susan Laing (7510C) Martha Terry (7510C)
Marshall Swindell (7510C) Dennis Edwards (7510C)

The Honorable Charles E. Grassley
United States Senate
Washington, DC 20510

Dear Senator Grassley:

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| CONCURRENCES | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| SYMBOL | 7506C | 7510C | 7506C | [illegible] | 7501-C | | | |
| SURNAME | [signature] | [signature] | [signature] | [signature] | [signature] | | | |
| DATE | 12/7/05 | 12/7/05 | 12/7/05 | 12-7-05 | 12-7-05 | | | |

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

As you know, in January 2003, the Pesticide Registration Improvement Act (PRIA) was enacted. This law established a fee structure and timelines for Agency review of applications for registration. Under PRIA, the due date for an Agency determination on the Stalosan F application is August 2006. At this time, the Agency is reviewing the data submitted to support the Stalosan F application. Barring any unforeseen issues, the Agency expects to make a final determination on the Stalosan F application in spring of 2006, well in advance of the PRIA due date.

Again, thank you for your letter and for bringing this matter to my attention. I hope that this information will prove to be helpful to you and Mr. Gabriel. If you have any further questions, please let me know or your staff may contact Betsy Henry in our Office of Congressional and Intergovernmental Relations at 202-564-7222.

Sincerely yours,

Susan B. Hazen
Principal Deputy Assistant Administrator

**Pages 46-48 *Internal deliberative information***

# Correspondence Management System

## Tracking Document

AA due date 9/29/05

**Control No.:** AL-05-001-7416
**Status:** Pending
**Due Date:** Dec 25, 2005
**Letter Date:** Oct 26, 2005
**Received Date:** Nov 22, 2005
**Close Date:** N/A
**# of Extensions:** 1
**Notes:** AA-OPPTS Prepare draft response for signature by the Assistant Administrator for OPPTS. CC: Lin Moos
**Alt No.:**
**File Code:** 141-A CONGRESSIONAL CORRESPONDENCE
**From:** Charles Grassley
Organization: United States Senate
Street: SH-135 Hart Senate Office Building
City/State/Zip: Washington / DC / 20510
Country: USA
**Committee:**
**Sub Committee:**
**Constituent:** GLEN GABRIEL
**To:**
**To Org:**
**Subject:** THE REGISTRATION OF STALOSAN F
**Signature:** AA-OPPTS-Assistant Administrator - OPPTS
**Signature Date:** N/A
**Instruction Codes:** AA-OPPTS-Prepare draft response for signature by the Assistant Administrator for OPPTS
**Instruction Notes:**
**Lead Author:** Ronald Jackson
**Lead Author Office:** OPPTS-OPP-FEAD-CSB
**Lead Author Due Date:** Dec 20, 2005
**Lead Author Assigned Date:** Nov 30, 2005
**Lead Author Complete Date:** Dec 07, 2005
**Lead Author Instruction:** AA-OPPTS-Prepare draft response for signature by the Assistant Administrator for OPPTS
**Supporting Author:**
**CC:** BETSY HENRY, Region 7

**Lead Info:**

| Assigner | Office | Assignee | Assigned Date | Due Date | Instructions | Completed Date |
|---|---|---|---|---|---|---|
| Cassaundra Eades | OCIR | OPPTS | Nov 22, 2005 | Dec 25, 2005 | AA-OPPTS-Prepare draft response for signature by the Assistant Administrator for OPPTS | N/A |
| Marilyn Mal- | OPPTS | OPPTS- | Nov 23, 2005 | Dec 20, 2005 | | Dec 07, 2005 |

| | | | | | | |
|---|---|---|---|---|---|---|
| loy Doretha Wood | OPPTS-OPP | OPP OPPTS-OPP-FEAD-CSB | Nov 28, 2005 | Dec 20, 2005 | AA_OPPTS - Prepare draft response for signature by the Assistant Administrator. Cc: Lin Moos | Dec 07, 2005 |
| Claire Gesalman | OPPTS-OPP-FEAD-CSB | Ronald Jackson | Nov 28, 2005 | Dec 20, 2005 | | Dec 07, 2005 |

### *Support Info:*

| Assigner | Office | Supporting Assignee | Assigned Date |
|---|---|---|---|
| No records found | | | |

### Assignment History:

| Assigner | Office | Action | Date of Action |
|---|---|---|---|
| Cassaundra Eades | OCIR | Assign OPPTS as lead office | Nov 22, 2005 |
| Marilyn Malloy | OPPTS | Assign OPPTS-OPP as lead office | Nov 23, 2005 |
| Doretha Wood | OPPTS-OPP | Assign OPPTS-OPP-FEAD-CSB as lead office | Nov 28, 2005 |
| Claire Gesalman | OPPTS-OPP-FEAD-CSB | Assign Ronald Jackson as lead | Nov 28, 2005 |
| Ronald Jackson | OPPTS-OPP-FEAD-CSB | Take task | Nov 30, 2005 |
| Ronald Jackson | OPPTS-OPP-FEAD-CSB | Sent for Review to Susan Laing | Nov 30, 2005 |
| Ronald Jackson | OPPTS-OPP-FEAD-CSB | Requested due date extension | Dec 01, 2005 |
| Claire Gesalman | OPPTS-OPP-FEAD-CSB | Sent to Cassaundra Eades for extension request | Dec 01, 2005 |
| Cynthia Gaines | OCIR | Changed due date from Dec 06, 2005 to Dec 13, 2005 | Dec 02, 2005 |
| Cassaundra Eades | OCIR | The due date extension request has been approved | Dec 05, 2005 |
| Susan Laing | OPPTS-OPP-AD | Review Approved by Susan Laing | Dec 07, 2005 |
| Ronald Jackson | OPPTS-OPP-FEAD-CSB | Finished response document | Dec 07, 2005 |
| Ronald Jackson | OPPTS-OPP-FEAD-CSB | Sent control to Claire Gesalman for approval | Dec 07, 2005 |
| Claire Gesalman | OPPTS-OPP-FEAD-CSB | Sent control back to Ronald Jackson for modification | Dec 07, 2005 |
| Ronald Jackson | OPPTS-OPP-FEAD-CSB | Resent control to Claire Gesalman for approval. | Dec 07, 2005 |
| Claire Gesalman | OPPTS-OPP-FEAD-CSB | Concur and sent control to Lin Moos for approval | Dec 07, 2005 |
| Lin Moos | OPPTS-OPP | Concur and sent control to Margie Fehrenbach for approval | Dec 07, 2005 |
| Margie Fehrenbach | OPPTS-OPP | Concur and sent control to anthony britten for approval | Dec 07, 2005 |

### Assignment Comments:

| Commentator | Comment | Date of Comment |
|---|---|---|
| Ronald Jackson | Based on reasons stated by the Antimicrobials Division (primarily that this is a complex issue, and the response will have to receive multiple reviews and concurrences), we request an extension to 12/20/05. requested extension date: 12/20/2005 | Dec 01, 2005 |

REPLY TO:
☑ 135 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510-1501
(202) 224-3744
TTY: (202) 224-4479
e-mail: chuck_grassley@grassley.senate.gov

☐ 721 FEDERAL BUILDING
210 WALNUT STREET
DES MOINES, IA 50309-2140
(515) 288-1145

☐ 206 FEDERAL BUILDING
101 1ST STREET SE
CEDAR RAPIDS, IA 52401-1227
(319) 363-6832

# United States Senate

CHARLES E. GRASSLEY

WASHINGTON, DC 20510-1501

REPLY TO:

☐ 103 FEDERAL COURTHOUSE BUILDING
320 6TH STREET
SIOUX CITY, IA 51101-1244
(712) 233-1860

☐ 210 WATERLOO BUILDING
531 COMMERCIAL STREET
WATERLOO, IA 50701-5497
(319) 232-6657

☐ 131 WEST 3RD STREET
SUITE 180
DAVENPORT, IA 52801-1413
(563) 322-4331

☐ 903 FEDERAL BUILDING
8 SOUTH 6TH STREET
COUNCIL BLUFFS, IA 51501-4204
(712) 322-7103

October 26, 2005

Mr. Charles Engebretsen
Assoc. Administrator of Congressional Affairs
Environmental Protection Agency
1200 Pennsylvania Avenue, NW, Room 3426 ARN
Washington, DC 20460

Dear Mr. Engebretsen:

Enclosed please find a communication from Glen Gabriel regarding the registration of Stalosan F.

I would appreciate any assistance you could provide pertaining to this matter. Please mark your return correspondence to the attention of Jarret Heil when responding to my office.

Thank you for your attention to my request.

Sincerely,

Chuck Grassley

Charles E. Grassley
United States Senator

CEG/jh
Enclosure

***Inert ingredient information may be entitled to confidential treatment***

Charles E. Grassley
United States Senator
135 Hart Senate Office Building
Washington, DC 20510

***Product ingredient source information may be entitled to confidential treatment***

Senator Charles E. Grassley:

It was a pleasure talking to you yesterday about our Company; our products (including Stalosan F™, the livestock odor abatement product); current issues related to US registration of Stalosan F™; and other related matters. I'm sure the time we spent together will be useful in helping us to resolve our problems. My colleagues and I certainly look forward to working with you, Senator Grassley, and any other persons who you believe can help our cause.

As mentioned, I indicated that I would formalize our telephone conversation by providing you a written description of our Company, the nature of Stalosan F™ (Material Specifications), the efficacy of Stalosan F™ (Effectiveness), and, as mentioned during the course of our telephone conversation, the current problems we have encountered in attempting to get our product registered with the EPA (Issues).

As you will see, there is no reason that this product should not be approved immediately by the EPA. It is with regard to this matter that we seek your immediate help. **We would be very pleased if you were to forward the attached draft letter to Stephen L. Johnson at the EPA.**

Our Company:

Our Company is an Illinois-chartered Limited Liability Company named "ArchAngel, LLC." The primary mission of our Company is to market and sell safe, natural products that promote animal health (and, hence, human health). At this time, our product portfolio is limited to importing and marketing the superb livestock odor abatement / dry disinfectant product produced by [redacted] company that has marketed and sold natural animal-health and livestock odor abatement products for many decades. In fact, [redacted]s the odor abatement product 'company of choice' for literally thousands of European livestock producers... and has been so for many, many years. Furthermore, ArchAngel, LLC and [redacted] have formalized a joint-agreement to manufacture Stalosan F™ in the United States, pending an EPA registration. The process has begun to secure a manufacturing site which would serve the Western Hemisphere and perhaps Asia.

Material Specifications of Stalosan F™:

Stalosan F™ is a powder of small particle size which is a mixture of [redacted] All of the active ingredients in the product are inorganic powders except for the perfume agent. The production process for this product is proprietary and covered by various patents. The product is imported into the United States as 55-pound bags stacked on pallets and placed inside containers.

***Product ingredient source information may be entitled to confidential treatment***

Importantly, note that this odor abatement product has significant disinfectant and antimicrobial properties – properties that contribute significantly to both the health of livestock and, the people who work in livestock production facilities. Additionally, unlike other common disinfectants, the product is completely safe for use in the presence of animals and human labor at all stages of production.

Effectiveness:

As mentioned, Stalosan F™ has both antimicrobial properties and odor abatement properties. Stalosan F™ essentially eliminates all odors arising from raising livestock in confined spaces by accomplishing the following:

- Inhibiting the metabolism and proliferation of bacteria and fungus through the use of its highly-reactive copper compounds
- Inhibiting the reproduction of bacteria, viruses, parasites, and fly-larvae through the use of minerals (Moler earth) that bind to the surface of these pests (rendering them inactive during the reproductive phase of these pests' life-cycle)
- Killing parasites, fly-larvae, insects, and worms (of various types) through the use of the sharp-edged crystalline shape of the product that penetrates the surface of these pests
- Killing bacteria and other pests through the use of its acidic surface
- Chemically inactivating urease, the enzyme found in swine and poultry urine that creates ammonia. And, note that it is the horrific ammonia odor emanating from swine and poultry operations that gives rise to the thousands of complaints registered by citizens in many communities throughout the United States.

Note also that all of the aforementioned items are substantiated with a voluminous amount of test data that has been performed at the expense of [redacted] in an effort to get approval (which they have done) for marketing and selling this product in many countries in Europe and in other parts of the world. In fact, the quantity and quality of research testing performed by [redacted] overwhelming and is available for viewing by the general public at the Company's web-site at [redacted]

Issues:

We have spent the past three years and a substantial amount of money in an attempt to get Stalosan F™ approved by the EPA for use in the United States. Our goal is to claim that our product:

- Eliminates the majority of odors normally associated with the production of livestock (again, in confined spaces)
- Creates a healthier environment for livestock production areas over which the product is employed

As a result of these two beneficial attributes, our marketing literature will further elaborate that our product thus promotes improved animal health, improved and more sanitary meat products originating from livestock operations that employ our product, and, hence, promotes improved human health.

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- The EPA should grant Stalosan F™ an antimicrobial registration quickly.

It's unfortunate that the product was not developed in the United States and that the EPA does not have any viable tests for products such as ours. But, in this case (livestock odor abatement and related animal health), we Americans have something to learn from our European 'cousins.'

Please help us get this product through the maze and roadblocks that we are facing in Washington. I'm sure that your constituents will become the rightful beneficiaries of a community with less odors, healthier animals, healthier meat products, and, most importantly, healthier families. Stalosan F™ really does work and it is time for the American public to benefit from this product.

Regards,

Glen H. Gabriel
ArchAngel, LLC
2735 Adirondack Dr.
Cedar Rapids, IA 52402
Ph - 319-360-3100
Fx – 319-364-8575

att: Draft Letter to EPA from respective Senator Grassley

United States
Environmental Protection Agency
Washington, D.C. 20460 Office of Prevention, Pesticides and Toxic Substances
Office of Pesticide Programs
Field and External Affairs Divison

Communication Services Branch
Telephone Number: (703) 305-5017
Fax Number: (703) 305-5558

# FAX COVER SHEET

Date: 11/29/05

TO

Name: Susan Laing

Organization: _____

Fax Phone Number: _____

Office Phone Number: _____

FROM

Name: Claire Gesalman

Office phone number: _____

Office room number: _____

Mail Code: 7506C

Number of pages (including this cover sheet): _____

Comments/Special Instructions: _____

# Correspondence Management System

Ronald

## Tracking Document

Decl

**Control No.:** AL-05-001-7416
**Status:** Pending
**Due Date:** ~~Dec 06, 2005~~
**Letter Date:** Oct 26, 2005
**Received Date:** Nov 22, 2005
**Close Date:** N/A
**# of Extensions:** 0
**Notes:**
**Alt No.:**
**File Code:** 141-A CONGRESSIONAL CORRESPONDENCE
**From:** Charles Grassley
Organization: United States Senate
Street: SH-135 Hart Senate Office Building
City/State/Zip: Washington / DC / 20510
Country: USA
**Committee:**
**Sub Committee:**
**Constituent:** GLEN GABRIEL
**To:**
**To Org:**
**Subject:** THE REGISTRATION OF STALOSAN F
**Signature:** AA-OPPTS-Assistant Administrator - OPPTS
**Signature Date:** N/A
**Instruction Codes:** AA-OPPTS-Prepare draft response for signature by the Assistant Administrator for OPPTS
**Instruction Notes:**
**Lead Author:**
**Lead Author Office:**
**Lead Author Due Date:** N/A
**Lead Author Assigned Date:** N/A
**Lead Author Complete Date:** N/A
**Lead Author Instruction:**
**Supporting Author:**
**CC:** BETSY HENRY, Region 7

**Lead Info:**

| Assigner | Office | Assignee | Assigned Date | Due Date | Instructions | Completed Date |
|---|---|---|---|---|---|---|
| Cassaundra Eades | OCIR | OPPTS | Nov 22, 2005 | Dec 06, 2005 | AA-OPPTS-Prepare draft response for signature by the Assistant Administrator for OPPTS | N/A |
| Marilyn Malloy | OPPTS | OPPTS-OPP | Nov 23, 2005 | Dec 01, 2005 | | N/A |

**Support Info:**

| Assigner | Office | Supporting Assignee | Assigned Date |
|---|---|---|---|
| No records found | | | |

## Assignment History:

| Assigner | Office | Action | Date of Action |
|---|---|---|---|
| Cassaundra Eades | OCIR | Assign OPPTS as lead office | Nov 22, 2005 |
| Marilyn Malloy | OPPTS | Assign OPPTS-OPP as lead office | Nov 23, 2005 |

## Assignment Comments:

| Commentator | Comment | Date of Comment |
|---|---|---|
| No records found | | |

Reply To:
☑ 135 Hart Senate Office Building
Washington, DC 20510-1501
(202) 224-3744
TTY: (202) 224-4479
E-mail: chuck_grassley@grassley.senate.gov

☐ 721 Federal Building
210 Walnut Street
Des Moines, IA 50309-2146
(515) 288-1145

☐ 206 Federal Building
101 1st Street SE
Cedar Rapids, IA 52401-1227
(319) 363-6832

# United States Senate

CHARLES E. GRASSLEY

WASHINGTON, DC 20510-1501

Reply To:
☐ 103 Federal Courthouse Building
320 6th Street
Sioux City, IA 51101-1244
(712) 233-1860

☐ 210 Waterloo Building
531 Commercial Street
Waterloo, IA 50701-5497
(319) 232-6657

☐ 721 West 3rd Street
Suite 150
Davenport, IA 52801-1419
(563) 322-4331

☐ 307 Federal Building
8 South 6th Street
Council Bluffs, IA 51501-4204
(712) 322-7103

October 26, 2005

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Assoc. Administrator of Congressional Affairs
Environmental Protection Agency
1200 Pennsylvania Avenue, NW, Room 3426 ARN
Washington, DC 20460

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Thank you for your attention to my request.

Sincerely,

Chuck Grassley

Charles E. Grassley
United States Senator

CEG/jh
Enclosure

***Product ingredient source information may be entitled to confidential treatment***

Charles E. Grassley
United States Senator
135 Hart Senate Office Building
Washington, DC 20510

***Inert ingredient information may be entitled to confidential treatment***

Senator Charles E. Grassley:

It was a pleasure talking to you yesterday about our Company; our products (including Stalosan F™, the livestock odor abatement product); current issues related to US registration of Stalosan F™; and other related matters. I'm sure the time we spent together will be useful in helping us to resolve our problems. My colleagues and I certainly look forward to working with you, Senator Grassley, and any other persons who you believe can help our cause.

As mentioned, I indicated that I would formalize our telephone conversation by providing you a written description of our Company, the nature of Stalosan F™ (Material Specifications), the efficacy of Stalosan F™ (Effectiveness), and, as mentioned during the course of our telephone conversation, the current problems we have encountered in attempting to get our product registered with the EPA (Issues).

As you will see, there is no reason that this product should not be approved immediately by the EPA. It is with regard to this matter that we seek your immediate help. **We would be very pleased if you were to forward the attached draft letter to Stephen L. Johnson at the EPA.**

Our Company:

Our Company is an Illinois-chartered Limited Liability Company named "ArchAngel, LLC." The primary mission of our Company is to market and sell safe, natural products that promote animal health (and, hence, human health). At this time, our product portfolio is limited to importing and marketing the superb livestock odor abatement / dry disinfectant product produced by [redacted] company that has marketed and sold natural animal-health and livestock odor abatement products for many decades. In fact, [redacted] is the odor abatement product 'company of choice' for literally thousands of European livestock producers... and has been so for many, many years. Furthermore, ArchAngel, LLC and [redacted] have formalized a joint-agreement to manufacture Stalosan F™ in the United States, pending an EPA registration. The process has begun to secure a manufacturing site which would serve the Western Hemisphere and perhaps Asia.

Material Specifications of Stalosan F™:

Stalosan F™ is a powder of small particle size which is a mixture of [redacted] All of the active ingredients in the product are inorganic powders except for the perfume agent. The production process for this product is proprietary and covered by various patents. The product is imported into the United States as 55-pound bags stacked on pallets and placed inside containers.

***Inert ingredient information may be entitled to confidential treatment***

Importantly, note that this odor abatement product has significant disinfectant and antimicrobial properties – properties that contribute significantly to both the health of livestock and, the people who work in livestock production facilities. Additionally, unlike other common disinfectants, the product is completely safe for use in the presence of animals and human labor at all stages of production.

Effectiveness:

As mentioned, Stalosan F™ has both antimicrobial properties and odor abatement properties. Stalosan F™ essentially eliminates all odors arising from raising livestock in confined spaces by accomplishing the following:

- Inhibiting the metabolism and proliferation of bacteria and fungus through the use of its highly-reactive copper compounds
- Inhibiting the reproduction of bacteria, viruses, parasites, and fly-larvae through the use of minerals (Moler earth) that bind to the surface of these pests (rendering them inactive during the reproductive phase of these pests' life-cycle)
- Killing parasites, fly-larvae, insects, and worms (of various types) through the use of the sharp-edged crystalline shape of the product that penetrates the surface of these pests
- Killing bacteria and other pests through the use of its acidic surface
- Chemically inactivating urease, the enzyme found in swine and poultry urine that creates ammonia. And, note that it is the horrific ammonia odor emanating from swine and poultry operations that gives rise to the thousands of complaints registered by citizens in many communities throughout the United States.

Note also that all of the aforementioned items are substantiated with a voluminous amount of test data that has been performed at the expense of [redacted] in an effort to get approval (which they have done) for marketing and selling this product in many countries in Europe and in other parts of the world. In fact, the quantity and quality of research testing performed by [redacted] is overwhelming and is available for viewing by the general public at the Company's web-site at [redacted]

Issues:

We have spent the past three years and a substantial amount of money in an attempt to get Stalosan F™ approved by the EPA for use in the United States. Our goal is to claim that our product:

- Eliminates the majority of odors normally associated with the production of livestock (again, in confined spaces)
- Creates a healthier environment for livestock production areas over which the product is employed

As a result of these two beneficial attributes, our marketing literature will further elaborate that our product thus promotes improved animal health, improved and more sanitary meat products originating from livestock operations that employ our product, and, hence, promotes improved human health.

In the United States, the EPA registers disinfectants for use as liquids – not powders, as is the case with Stalosan F™. These liquid disinfectants are subjected to a standard test that requires, among other items, that the disinfectant kill all of a specific amount of a control pathogen in a specified period of time. Stalosan F™, being a powder, has no hope of working as fast as a liquid disinfectant. However, the product is more effective (kills more pathogens / works longer) than any known liquid disinfectant for its intended use. Moreover, it is a complex mixture of naturally occurring products that have, individually or collectively, no deleterious effects on humans, animals, or the environment. Specifically, none of the active ingredients in the product are – by EPA definitions – hazardous ingredients.

Our contentions are as follows:

- Stalosan F™ is a powder 'antimicrobial' (and odor abatement product) and should not be subjected to the same tests as are performed on liquid disinfectants.
- The EPA should grant Stalosan F™ an antimicrobial registration quickly.

It's unfortunate that the product was not developed in the United States and that the EPA does not have any viable tests for products such as ours. But, in this case (livestock odor abatement and related animal health), we Americans have something to learn from our European 'cousins.'

Please help us get this product through the maze and roadblocks that we are facing in Washington. I'm sure that your constituents will become the rightful beneficiaries of a community with less odors, healthier animals, healthier meat products, and, most importantly, healthier families. Stalosan F™ really does work and it is time for the American public to benefit from this product.

Regards,

Glen H. Gabriel
ArchAngel, LLC
2735 Adirondack Dr.
Cedar Rapids, IA 52402
Ph - 319-360-3100
Fx – 319-364-8575

att: Draft Letter to EPA from respective Senator Grassley

# Fee for Service

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 33

| | |
|---|---|
| Receipt No. S- | 783560 |
| EPA File Symbol/Reg. No. | 5F6982 |
| Pin-Punch Date: | 8/25/05 |

☐ This item is NOT subject to FFS action.

**Action Code:**

Requested:

Granted: A46.0 kr

Amount Due: ~~$10,000~~

**Parent/Child Decisions:**

Reviewer: Henson Date: 8/26/05

Remarks:

*Please read instructions on reverse before completing form.* Form Approved, OMB No. 2070-0060

**EPA** United States **Environmental Protection Agency** Washington, DC 20460

☒ **Registration** ☐ **Amendment** ☐ **Other**

OPP Identifier Number: 296838

## Application for Pesticide - Section I

| 1. Company/Product Number | 2. EPA Product Manager | 3. Proposed Classification |
|---|---|---|
| 75526- R | Marshall Swindell | ☒ None ☐ Restricted |
| 4. Company/Product (Name) | PM# 33 ~~33~~ | |
| **ArchAngel LLC – Stalosan F** | | |

5. Name and Address of Applicant *(Include ZIP Code)*
**ArchAngel LLC**
**636 Hampshire, Suite 208**
**Quincy, IL 62301**
***PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW***
☒ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

## Section – II

- ☒ Amendment – Explain below.
- ☐ Resubmission in response to Agency letter dated _____
- ☐ Notification – Explain below.
- ☐ Final printed labels in response to Agency letter dated _____
- ☐ "Me Too" Application
- ☐ Other - Explain below

**Explanation**: Use additional page(s) if necessary. (For section I and Section II.)
This is an old chemical registration with some new language for an existing animal confinement areas use. The product is being registered for non-public health uses, with the language agreed to in the pre-application process. The registrant has provided all required product chemistry information and acute toxicity data, using cite all for the generic data for copper sulfate pentahydrate. The category for this under PRIA should be category A54. The normal fee would be $4,000, but we have provided small business information to request a waiver. Please contact me at bbrennis@lewisharrison.com when the fee determination is complete.

## Section – III

1. Material This Product Will Be Packaged In:

| Child-Resistant Packaging | Unit Packaging | Water Soluble Packaging | 2. Type of Container |
|---|---|---|---|
| ☐ Yes* ☒ No | ☐ Yes ☒ No | ☐ Yes ☒ No | ☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☒ Other – Plastic bag/paper cover |
| *Certification must be submitted | If "Yes" Unit Packaging wgt. / No. per container | If "Yes" Package wgt / No. per container | |

| 3. Location of Net Contents Information | 4. Size(s) Retail Container | 5. Location of Label Directions |
|---|---|---|
| ☐ Label ☒ Container | ounces of product 25 kg. Net weight | ☒ On Label ☐ On labeling accompanying product |

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☒ Stenciled ☐ Other _____

## Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

| Name | Title | Telephone No. (Include Area Code) |
|---|---|---|
| Robert S. Brennis, Lewis & Harrison 122 C St. NW, Suite 740, Washington, DC 20001 | Agent for ArchAngel LLC | 202-393-3903 ext 20 |

**Certification**
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| 2. Signature | 3. Title | 6. Date Application Received |
|---|---|---|
| | Agent for ArchAngel LLC | (Stamped) |
| 4. Typed Name: Robert S. Brennis | 5. Date: *April 20, 2005* | |

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete — White- EPA File Copy (original) — Yellow- Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 5, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-356769
EPA File Symbol or Registration Number: 75526-R
Product Name: STALOSAN F
EPA Receipt Date: 02-May-2005
EPA Company Number: 75526
Company Name: ARCHANGEL LLC

KENT ADAMS
ARCHANGEL LLC
636 HAMPSHIRE STREET, SUITE 208
QUINCY, IL 62301

SUBJECT: Receipt of Registration Application and 100% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application for registration and 100% small business waiver request. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A46

NEW USE;WITH EXEMPTION;NEW FOOD USE;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If the determination indicates that payment is due, you will receive instructions for submitting payment at that time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-6432.

Sincerely,

Front End Processing Staff
Information Resources and Services Division

# Fee for Service

| This package includes the following | for Division |
|---|---|
| [X] New Registration | ~~[X] RD~~ |
| [ ] Amendment | [X] AD |
| [X] Waiver Request and type | [ ] BPPD |
| [ ] 100% [ ] 50% [ ] IR-4 [ ] Minor [ ] Fed/state | Risk Mgr. ~~33~~ |

Receipt Nos. S- 778306

EPA File Symbol/Reg. No. 75526-R

Pin-Punch Date: 5/2/05

[ ] This item is NOT subject to FFS action.

| Action Code: | Parent/Child Decisions: |
|---|---|
| Requested: A-~~69~~ 46 | |
| Granted: A-~~69~~ 46 | |
| Amount due: $ ~~0000~~ 10,000 | |

[ ] Voluntary Payment Request % Reduction _____

Reviewer: [illegible] / K. Leung Date: 5-4-05

Remarks: (use back if needed)

46/B-2-1

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, D.C. 20460**

May 27, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-356769
EPA File Symbol or Registration Number: 75526-R
Product Name: STALOSAN F
EPA Application Receipt Date: 02-May-2005
EPA Waiver Request Receipt date: 02-May-2005
EPA Company Number: 75526
Company Name: ARCHANGEL LLC

KENT ADAMS
ARCHANGEL LLC
636 HAMPSHIRE STREET, SUITE 208
QUINCY, IL 62301

SUBJECT: Approval of Waiver Request

Dear Registrant:

The Office of Pesticide Programs has approved your request for 100% waiver of the pesticide registration fee associated with the action referenced above. The decision review period for this action begins on the date of this letter.

The Action has been identified as Action Code: A46

NEW USE;WITH EXEMPTION;NEW FOOD USE

If you have any questions, please contact Pesticide Registration Service Fee Ombudsman, at (703) 308-6432.

Sincerely,

for Arnold E. Layne, Director
Information Resources and Services Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice**: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date 04/27/05

EPA Reg. No./File Symbol 75526-R



Applicant's/Registrant's Name & Address:
***ArchAngel LLC***
**636 Hampshire, Suite 208**
**Quincy, IL 62301**

Product
***Stalosan F***

Ingredient(s): **a) Copper Sulfate Pentahydrate (CAS #7758-99-8)**

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| 830.1550/61-1 | Product Identity and Composition | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 830.1600/61-2 | Description of the Materials Used to Produce the Product | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 830.1650/61-2 | Description of the Manufacturing Process | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 830.1670/61-3 | Discussion of Formation of Impurities | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 830.1700/62-1 | Preliminary Analysis | Not Required | --- | --- | |
| 830.1750/62-2 | Certified Limits | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 830.1800/62-3 | Enforcement Analytical Method | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 830.6302/63-2 | Color | *To be assigned* | ArchAngel (Co. #75526) | --- | |
| 830.6303/63-3 | Physical State | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 830.6304/63-4 | Odor | *To be assigned* | ArchAngel (Co. #75526) | --- | |
| 830.7300/63-7 | Density/Relative Density/Bulk Density | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 830.7000/63-12 | pH | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 830.6313/63-13 | Stability | *To be assigned* | ArchAngel (Co. #75526) | --- | |
| 830.6314/63-14 | Oxidation/Reduction: Chemical Compatibility | Not Required | --- | --- | |
| 830.6316/63-16 | Explodability | Not Required | --- | --- | |
| 830.6317/63-17 | Storage Stability | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 830.6319/63-19 | Miscibility | Not Required | --- | --- | |
| 830.6320/63-20 | Corrosion Characteristics | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 830.6321/63-21 | Dielectric Breakdown Voltage | Not Required | --- | --- | |
| 870.1100/81-1 | Acute Oral Toxicity | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 870.1200/81-2 | Acute Dermal Toxicity | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 870.1300/81-3 | Acute Inhalation Toxicity | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 870.2400/81-4 | Primary Eye Irritation | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 870.2500/81-5 | Primary Dermal Irritation | *To be assigned* | ArchAngel (Co. #75526) | OWN | |
| 870.2600/81-6 | Skin Sensitization | *To be assigned* | ArchAngel (Co. #75526) | OWN | |

Signature

Name and Title: **Robert S. Brennis, Lewis & Harrison**
**Agent for ArchAngel LLC**

Date 4/27/05

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

| Date 04/27/05 | EPA Reg. No./File Symbol 75526-R | Page 2 of 2 |
|---|---|---|
| Applicant's/Registrant's Name & Address:<br>**ArchAngel LLC**<br>**636 Hampshire, Suite 208**<br>**Quincy, IL 62301** | Product<br>**Stalosan F** | |

Ingredient(s): **a) Copper Sulfate Pentahydrate (CAS #7758-99-8)**

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|

ArchAngel is using the Cite All method of support for generic data for Copper Sulfate Pentahydrate not covered by the Product Chemistry and Acute Toxicity data generated by the company. The use site for this product is indoor animal containment areas.

We have offered compensation to all companies on the data submitters list which is attached to this form.

| Signature | Name and Title: **Robert S. Brennis, Lewis & Harrison Agent for ArchAngel LLC** | Date 4/27/05 |
|---|---|---|

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

| | | |
|---|---|---|
| COMPANY# | 035896 | PHIBRO-TECH INC<br>ATTN: RONALD MILLER |
| * DATA TYPES * | | 65 CHALLENGER ROAD, 3RD FLOOR |
| EU AT EC FW EF OT | | RIDGEFIELD PARK, NJ 07660 |
| | XX XX | |
| COMPANY# | 037818 | LIQUID CHEMICAL CORP. |
| * DATA TYPES * | | 13415 S 11TH AVENUE |
| EU AT EC FW EF OT | | HANFORD, CA 93230 |
| XX | XX | |
| COMPANY# | 041246 | BAY CHEMICAL & SUPPLY COMPANY |
| * DATA TYPES * | | PO BOX 1160 |
| EU AT EC FW EF OT | | ODEM, TX 78370 |
| | XX | |
| COMPANY# | 042414 | TECK COMINCO AMERICAN INC. |
| * DATA TYPES * | | PO BOX 3087 |
| EU AT EC FW EF OT | | SPOKANE, WA 99220 |
| XX XX XX XX XX | | |
| COMPANY# | 046923 | OLD BRIDGE CHEMICAL CO. |
| * DATA TYPES * | | PO BOX 175 |
| EU AT EC FW EF OT | | OLD BRIDGE, NJ 08857 |
| | XX | |
| COMPANY# | 049538 | LEWIS & HARRISON, LLC<br>Agent for: PHYTON CORPORATION |
| * DATA TYPES * | | 122 C STREET, NW, SUITE 740 |
| EU AT EC FW EF OT | | WASHINGTON, DC 20001 |
| XX | XX | |
| COMPANY# | 051036 | MICRO-FLO COMPANY LLC |
| * DATA TYPES * | | 530 OAK COURT DRIVE |
| EU AT EC FW EF OT | | MEMPHIS, TN 38117 |
| | XX | |
| COMPANY# | 056501 | COPPER SULFATE TASK FORCE |
| * DATA TYPES * | | PO BOX 5209 |
| EU AT EC FW EF OT | | VALDOSTA, GA 316035209 |
| XX XX | XX | |
| COMPANY# | 060059 | TECK COMINCO METALS LTD. |
| * DATA TYPES * | | PO BOX 5126 |
| EU AT EC FW EF OT | | VALDOSTA, GA 316035126 |
| XX XX XX XX | | |
| COMPANY# | 061943 | CHEM-A-CO INC |
| * DATA TYPES * | | PO BOX 1099 |
| EU AT EC FW EF OT | | MONTICELLO, IN 47960 |
| XX | | |
| COMPANY# | 063394 | AMERICAN CHEMISTRY COUNCIL BIOCIDES PANEL |
| * DATA TYPES * | | 1300 WILSON BLVD |
| EU AT EC FW EF OT | | ARLINGTON, VA 22209 |
| | XX | |
| COMPANY# | 066607 | SPRAY DRIFT TASK FORCE |
| * DATA TYPES * | | 1900 K STREET, NW |
| EU AT EC FW EF OT | | WASHINGTON, DC 20006 |
| | XX | |
| COMPANY# | 066675 | MAGNA-BON II, LLC |
| * DATA TYPES * | | 1531 NW 25TH DRIVE |
| EU AT EC FW EF OT | | OKEECHOBEE, FL 34972 |
| | XX | |
| COMPANY# | 067712 | ZODIAC POOL CARE, INC. |
| * DATA TYPES * | | 2026 NW 25TH AVENUE |
| EU AT EC FW EF OT | | POMPANO BEACH, FL 33069 |

```
COMPANY#   001270   PHELPS DODGE REFINING CORPORATION
*  DATA  TYPES  *  PO BOX 20001
EU AT EC FW EF OT  EL PASO, TX 79998
   XX XX XX XX XX

COMPANY#   003238   AGRICO CHEMICAL CO.
*  DATA  TYPES  *  PO BOX 60031
EU AT EC FW EF OT  NEW ORLEANS, LA 70160
             XX

COMPANY#   006991   ROCKWIN PROD COMPANY INC
*  DATA  TYPES  *  73 OSER AVENUE
EU AT EC FW EF OT  HAUPPAUGE, NY 11787
   XX

COMPANY#   007152   SEABOARD INDUSTRIES
*  DATA  TYPES  *  185 VAN WINKLE AVE.
EU AT EC FW EF OT  HAWTHORNE, NJ 07507
                XX

COMPANY#   007364   GLB POOL & SPA
                    W175 N11163 STONEWOOD DRIVE
*  DATA  TYPES  *  SUITE 234
EU AT EC FW EF OT  GERMANTOWN, WI 53022
      XX XX XX XX

COMPANY#   007792   BRAZOS ASSOCIATES, INC.
                    Agent for: ROBBIC LABS, INC.
*  DATA  TYPES  *  1806 AUBURN DRIVE
EU AT EC FW EF OT  CARROLLTON, TX 75007
                XX

COMPANY#   008622   AMERIBROM, INC
*  DATA  TYPES  *  2115 LINWOOD AVENUE
EU AT EC FW EF OT  FORT LEE, NJ 07024
   XX           XX

COMPANY#   008901   GRIFFIN CORP
*  DATA  TYPES  *  13701 ALMEDA RD
EU AT EC FW EF OT  HOUSTON, TX 77045
   XX XX XX    XX

COMPANY#   008959   APPLIED BIOCHEMISTS
                    W175 N11163 STONEWOOD DRIVE
*  DATA  TYPES  *  SUITE 234
EU AT EC FW EF OT  GERMANTOWN, WI 53022
   XX XX XX XX

COMPANY#   010356   CHEMICAL SPECIALTIES, INC.
*  DATA  TYPES  *  ONE WOODLAWN GREEN
EU AT EC FW EF OT  CHARLOTTE, NC 28217
             XX XX

COMPANY#   010691   MARJON & ASSOCIATES
*  DATA  TYPES  *  PO BOX 791
EU AT EC FW EF OT  MARICOPA, CA 93252
   XX           XX

COMPANY#   019214   CONSUMER CHEMICAL CORPORATION
*  DATA  TYPES  *  9 BRIDLE LANE
EU AT EC FW EF OT  POUGHKEEPSIE, NY 12603
             XX XX

COMPANY#   034076   DAYS EASE HOME PRODUCTS CORPORATION
*  DATA  TYPES  *  12460 VICTORY BLVD
EU AT EC FW EF OT  N HOLLYWOOD, CA 91606
             XX
```

XX XX

| | |
|---|---|
| COMPANY# 070264 | ALTIVIA CORPORATION |
| * DATA TYPES * | 100 LOUISANA, SUITE 3150 |
| EU AT EC FW EF OT | HOUSTON, TX 77002 |
| XX | |

| | |
|---|---|
| COMPANY# 071146 | CNM TECHNOLOGIES |
| * DATA TYPES * | 94 GARDINERS AVE - STE 242 |
| EU AT EC FW EF OT | LEVITTOWN, NY 11756 |
| XX | |

| | |
|---|---|
| COMPANY# 071754 | OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE, L.L.C. |
| * DATA TYPES * | 1350 I STREET, N.W. |
| EU AT EC FW EF OT | WASHINGTON, DC 20005 |
| XX | |

| | |
|---|---|
| COMPANY# 071755 | AGRICULTURAL REENTRY TASK FORCE |
| * DATA TYPES * | 1350 I STREET, N.W. |
| EU AT EC FW EF OT | WASHINGTON, DC 20005 |
| XX | |

| | |
|---|---|
| COMPANY# 073020 | EMRON CORPORATION |
| * DATA TYPES * | PO BOX 675 |
| EU AT EC FW EF OT | PITTSTOWN, NJ 08867 |
| XX | |

| | |
|---|---|
| COMPANY# 073123 | CRYSTAL CLEAR POOL & SPA C/O CAPO IND. |
| | C/O A. DUIE PYLE WAREHOUSE |
| * DATA TYPES * | 4087 LOWER VALLEY ROAD |
| EU AT EC FW EF OT | PARKESBURG, PA 19365 |
| XX | |

| | |
|---|---|
| COMPANY# 074962 | SCIENTIFIC & REGULATORY CONSULTANTS, INC. |
| | Agent for: BENT OAK FARM SUPPLY |
| * DATA TYPES * | PO BOX 1014 |
| EU AT EC FW EF OT | COLUMBIA CITY, IN 46725 |
| XX | |

| | |
|---|---|
| COMPANY# 075234 | AGRICULTURAL HANDLER EXPOSURE TASK FORCE |
| * DATA TYPES * | 1156 FIFTEENTH STREET, NW, SUITE 400 |
| EU AT EC FW EF OT | WASHINGTON, DC 20005 |
| XX | |

| CHEMICAL | CHEMICAL NAME |
|---|---|
| 026401 | Copper sulfate pentahydrate |

| | | |
|---|---|---|
| COMPANY# | 000061 | KOPPERS COMPANY, INCORPORATED |
| * DATA TYPES * | | 1201 KOPPERS BUILDING |
| EU AT EC FW EF OT | | PITTSBURGH, PA 15219 |
| XX XX XX XX | | |

| | | |
|---|---|---|
| COMPANY# | 001109 | BOLIDEN INTERTRADE INC |
| * DATA TYPES * | | 3379 PEACHTREE RD NE, SUITE 300 |
| EU AT EC FW EF OT | | ATLANTA, GA 30326 |
| XX | XX XX XX | |

| | | |
|---|---|---|
| COMPANY# | 001258 | ARCH CHEMICALS, INC. |
| * DATA TYPES * | | 1955 LAKE PARK DRIVE |
| EU AT EC FW EF OT | | SMYRNA, GA 30080 |
| | XX | |

90-20-90

943

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

| Date 04/27/05 | EPA Reg. No./File Symbol 75526-R | Page 1 of 2 |
|---|---|---|
| Applicant's/Registrant's Name & Address:<br>**ArchAngel LLC**<br>**636 Hampshire, Suite 208**<br>**Quincy, IL 62301** | Product<br>**Stalosan F** | |

Ingredient(s): **a) Copper Sulfate Pentahydrate (CAS #7758-99-8)**

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|
| | | | Product Identity and Composition | OWN | |
| | | | Description of the Materials Used to Produce the Product | OWN | |
| | | | ArchAngel (Co. #75526) | OWN | |
| | | | ArchAngel (Co. #75526) | OWN | |
| | | | --- | --- | |
| | | | ArchAngel (Co. #75526) | OWN | |
| | | | ArchAngel (Co. #75526) | OWN | |
| | | | ArchAngel (Co. #75526) | --- | |
| | | | ArchAngel (Co. #75526) | OWN | |
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| | | | ArchAngel (Co. #75526) | OWN | |
| | | | ArchAngel (Co. #75526) | OWN | |
| | | | ArchAngel (Co. #75526) | OWN | |
| | | | ArchAngel (Co. #75526) | OWN | |

| Signature | Name and Title: **Robert S. Brennis, Lewis & Harrison Agent for ArchAngel LLC** | Date 4/27/05 |
|---|---|---|

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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## DATA MATRIX

| Date 04/27/05 | EPA Reg. No./File Symbol 75526-R | Page 2 of 2 |
|---|---|---|
| Applicant's/Registrant's Name & Address:<br>**ArchAngel LLC**<br>**636 Hampshire, Suite 208**<br>**Quincy, IL 62301** | Product<br>**Stalosan F** | |

Ingredient(s): **a) Copper Sulfate Pentahydrate (CAS #7758-99-8)**

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|---|---|---|---|---|---|

ArchAngel is using the Cite All method of support for generic data for Copper Sulfate Pentahydrate not covered by the Product Chemistry and Acute Toxicity data generated by the company. The use site for this product is indoor animal containment areas.

We have offered compensation to all companies on the data submitters list which is attached to this form.

| Signature | Name and Title: **Robert S. Brennis, Lewis & Harrison Agent for ArchAngel LLC** | Date 4/27/05 |
|---|---|---|

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

LEWIS & HARRISON
Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

April 20, 2005 ***HAND DELIVERED***

Document Processing Desk [APPL]
Office of Pesticide Programs (7504C)
Registration Division
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 Bell Street
Arlington, VA 22202

**ATTENTION:** **Marshall Swindell**
**Product Manager, Team 33**

***SUBJECT:*** ***ArchAngel LLC***
***Stalosan F (EPA Reg. No. 75526-R)***
***Application for Pesticide Registration of a New End-Use Product***
***Old Chemical Registration***

Dear Mr. Swindell:

On behalf of ArchAngel LLC, we are submitting an application to register a new end-use product, **Stalosan F**. The proposed **Stalosan F** product is intended for use as a fungicide bacteristat for livestock housing facilities. This is an old chemical application with some new language for an existing animal confinement areas use. The product is being registered for non-public health uses, with the language agreed to in the pre-application process. The registrant has provided all required product chemistry information and acute toxicity data, using cite all for the generic data for copper sulfate pentahydrate.

**A) SIMILARITY TO REGISTERED PRODUCTS:**

The formulation for **Stalosan F** is not identical to that of any specific copper sulfate pentahydrate product, but the same uses are employed by **Earthtec Algicide/bacteristat (EPA Reg. No. 64962-1).** We have supplied product specific data.

**B) DATA REQUIREMENTS:**

Product-specific chemistry studies, 6 acute toxicity studies, and an accelerated storage stability study for **Stalosan F** are included with this application package. I have attached a note from Bob Turpin, which indicates that the preliminary analysis (5 batches) is not required because the product is a formulated product and the active ingredient is considered to be a commonly

used chemical. To fulfill the remaining data requirements for **Stalosan F**, we are relying on the "cite all method" of support.

**D) REGISTRATION FEES:**

This product is a simple old chemical registration with product chemistry data for review. The category for this under PRIA should be category A54. The normal fee would be $4,000, but we have provided small business information to request a waiver.

Please contact me at rbrennis@lewisharrison.com for confirmation of the waiver.

**D) SUPPORTING DOCUMENTS:**

Please find enclosed the following documents to support the registration of **Stalosan F**:

1) Transmittal Document;
2) Application for Pesticide Registration (OPP ID. 296838);
3) Registration Fee Waiver Materials
4) Copy of the Minutes from the Pre-application Meeting.
5) Two (2) copies of the Confidential Statement of Formula;
6) Five (5) copies of the proposed product label;
7) Certification with Respect to Citation of Data form;
8) Data Matrix (product specific citations and cite all, agency and public);
9) Three (3) copies of the Prod chem. study;
10) Three (3) copies of the physical and chemical properties study;
11) Three (3) copies of the six acute toxicity studies;
12) Three (3) copies of the accelerated storage stability study; and
13) Two (2) copies of the note from product chemistry regarding requirements.

If you have any questions about the enclosed registration submission, please contact me either by telephone at 202-393-3903 ext. 20 or by e-mail at rbrennis@lewisharrison.com.

Sincerely,

Robert S. Brennis
Agent for,
ArchAngel LLC

Enclosures

# EPA TRANSMITTAL DOCUMENT

| | |
|---|---|
| SUBMISSION DATED: | **April 20, 2005** |
| STUDY SUBMITTER: | **ArchAngel LLC** |
| SUBMITTED IN SUPPORT OF: | **Stalosan F** |
| EPA REGISTRATION NO.: | **75526-R** |
| REGULATORY ACTION: | **Application for Pesticide Registration – Old Chemical** |
| STUDIES SUBMITTED: | **9 Volumes** |
| STUDY VOLUME 1 of 9: | **Chemistry Data for Stalosan F (April 8, 2005) by Robert Brennis; 13 pages non-confidential, 40 pages confidential appendix.**<br><br>***US EPA Guidelines 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, & 830.1800***<br><br>MRID Number:_____ |
| STUDY VOLUME 2 of 9: | **Physical and Chemical Characteristics of Stalosan F (March 11, 2005) by Catherine Wo, Ph.D. 15 pages**<br><br>***US EPA Guidelines 830.6302, 830.6303, 830.6304, 830.6314, 830.7000, & 830.7300***<br><br>MRID Number:_____ |
| STUDY VOLUME 3 of 9: | **Acute Oral Toxicity Up and Down Procedures in Rats (March 10, 2005) by Daniel J. Merkel; 15 pages**<br><br>***US EPA Guidelines 830.1100 (2002)***<br><br>MRID Number:_____ |
| STUDY VOLUME 4 of 9: | **Acute Dermal Toxicity Study in Rats – Limit Test (March 10, 2005) by Daniel J. Merkel; 15 pages**<br><br>***US EPA Guidelines 830.1200 (1998)***<br><br>MRID Number:_____ |
| STUDY VOLUME 5 of 9: | **Acute Inhalation Toxicity Study in Rats – Limit Test (March 10, 2005) by Daniel J. Merkel; 23 pages**<br><br>***US EPA Guidelines 830.1300 (1998)***<br><br>MRID Number:_____ |

STUDY VOLUME 6 of 9: **Primary Eye Irritation Study in Rabbits (March 10, 2005) by Daniel J. Merkel; 16 pages**

***US EPA Guidelines 830.2400 (1998)***

MRID Number:_____

STUDY VOLUME 7 of 9: **Primary Skin Irritation Study in Rabbits (March 10, 2005) by Daniel J. Merkel; 16 pages**

***US EPA Guidelines 830.2500 (1998)***

MRID Number:_____

STUDY VOLUME 8 of 9: **Dermal Sensitization Study in Guinea Pigs (Buehler Method) (March 10, 2005) by Daniel J. Merkel; 24 pages**

***US EPA Guidelines 830.2600 (2003)***

MRID Number:_____

STUDY VOLUME 9 of 9: **Accelerated Storage Stability Study (February 3, 2005) by Catherine Wo, Ph.D.; 17 pages**

***US EPA Guidelines 830.6313 & 830.6317***

MRID Number:_____

[bracketed phrases are optional text]

# Stalosan F

## Adsorb Plus (additional brand name)

**For use in livestock housing, to improve the external environment and flooring conditions around animals.**

Lack of moisture assists in the reduction of non-public health microorganisms
**Stalosan F** adsorbs moisture, ammonia, hydrogen sulphide and other gases.
[Inhibits the growth of bacteria and fungi]
[Eliminates odor causing bacteria, fungi, mold, and mildew]
[Inhibits the growth of non public health bacteria]
[Inhibits the growth of fungi]
[Reduces ammonia and moisture]
[Eliminates odor causing bacteria, fungi, mold, and mildew]
[Eliminates odors associated with bacteria, mold, and mildew]
[Deodorizes], [Deodorizer]
[Controls and inhibits odor causing bacteria, fungi, mold, and mildew]

# Caution

## Keep Out of Reach of Children

## FIRST AID

**If in eyes:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

## Active Ingredients:

Copper Sulfate Pentahydrate*.....2.66%
Inert Ingredients..... 98.54%
TOTAL.....100.00%
* Metallic Copper Equivalent Equal-----0.68%

EPA Reg. No. 75526-R

EPA est. No. 75613-DNK-01

ArchAngel LLC
636 Hampshire, Suite 208
Quincy, IL 62301
phone number

**25 Kg. Net Wt.**

# PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.

# ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic organisms.

# Directions for Use

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Add 1 pound of **Stalosan F** to every 100 sq. ft. If the area is badly affected, increase the dosage slightly. Initially apply **Stalosan F** once a day for 3 days. Continue treatment once a week, thereafter. **Stalosan F** can be applied while animals are present.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in a cool, dry area away from direct sunlight and heat to avoid deterioration and in an area inaccessible to children.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Once bag is empty, dispose of in a sanitary landfill or by incineration, or; if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Form Approved OMB No. 2070-0060

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M Street, S.W.**
**WASHINGTON, D.C. 20460**

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## Certification with Respect to Citation of Data

| Applicant's/Registrant's Name, Address and Telephone Number | EPA Registration Number/ File Symbol |
|---|---|
| Kent Adams, ArchAngel LLC, 636 Hampshire, Suite 208<br>Quincy, IL 62301 | 75526-R |
| Active Ingredient(s) and/or representative test compound(s):<br>**Copper sulfate pentahydrate** | Date 4/15/05 |
| General use pattern(s) (list all those claimed for this product using 40 CFR Part 158)<br>**Animal Containment Facility** | Product Name<br>**Stalosan F** |

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☒ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

**I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.**

| Signature | Date | Typed or Printed Name and Title |
|---|---|---|
| | 4-15-05 | Kent Adams Secretary/Treasurer |



EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

From: Turpin.Robert@epamail.epa.gov
Sent: Thursday, October 28, 2004 4:20 PM
To: Robert Brennis
Subject: Data requirements for a formulated copper sulfate product

Bob,

As promised, I conferred with Karen Hicks, Team Leader of the Chemistry and Toxicology Team, and the following was determined based on the information you provided:

(a) 830.1700 - Preliminary Analysis (5 batches) is not required because the product is a formulated product and the active ingredient is considered to be a commonly used chemical. In the absence of this requirement, however, the Agency will require a Certificate of Analysis (CoA) and a Material Safety Data Sheet (MSDS);

(b) Series 830, Group A requirements are necessary with your submission. Further, because the source of the active ingredient is not registered with the Agency Group B data is also required. If the applicant chooses to self-certify Group B data he may do so using the forms provided by the Agency on its web-site. Otherwise, such data must be developed under GLP standards;

(c) 830.6317 - Storage Stability is required, however, the applicant may choose to perform the accelerated test protocol at an elevated temperature (40 to 54 degrees C). This requirement is a GLP study. The study of corrosion characteristics of the product in its packaging materials is usually combined with the study of storage stability.

I hope this answers your questions. Should you have further questions, please do not hesitate to contact.

Bob

From: Turpin.Robert@epamail.epa.gov
Sent: Thursday, October 28, 2004 4:20 PM
To: Robert Brennis
Subject: Data requirements for a formulated copper sulfate product

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(a) 830.1700 - Preliminary Analysis (5 batches) is not required because the product is a formulated product and the active ingredient is considered to be a commonly used chemical. In the absence of this requirement, however, the Agency will require a Certificate of Analysis (CoA) and a Material Safety Data Sheet (MSDS);

(b) Series 830, Group A requirements are necessary with your submission. Further, because the source of the active ingredient is not registered with the Agency Group B data is also required. If the applicant chooses to self-certify Group B data he may do so using the forms provided by the Agency on its web-site. Otherwise, such data must be developed under GLP standards;

(c) 830.6317 - Storage Stability is required, however, the applicant may choose to perform the accelerated test protocol at an elevated temperature (40 to 54 degrees C). This requirement is a GLP study. The study of corrosion characteristics of the product in its packaging materials is usually combined with the study of storage stability.

I hope this answers your questions. Should you have further questions, please do not hesitate to contact.

Bob

LEWIS &
HARRISON
Consultants in Government Affairs

122 C Street, N.W. Suite 740
Washington, DC 20001
telephone 202.393.3903
fax 202.393.3906

October 28, 2004

Tony Kish
U.S. EPA
Crystal Mall 2 (7510C)
1801 Bell Street
Arlington, VA 22202

Subject: ArchAngel LLC Application for Registration
Stolasan F
Label Claims

Dear Tony:

We had agreed to send prospective non-public health claims that may be acceptable on the product we intend on registering. If you remember, although we have data that shows the product works to remove bacteria and viruses, it doesn't meet the disinfection or sanitization standard set by the Agency. This product, however, is highly beneficial for use in animal containment facilities and we need some reasonable claims in order to register this product and bring it to the marketplace.

Below is a chart to identify the claims and reasons why the claims should be acceptable. Please review these claims so that we may discuss how these claims will be shown on our proposed label.

| Claims | Justification |
|---|---|
| Prevents cross-contamination between treated surfaces claim | Tony Kish suggested in the meeting |
| Adjunct to manual disinfection | Nancy Whyte suggested in the meeting |
| Lack of moisture assists in the reduction of microorganisms | Nancy Whyte suggested in the meeting |
| moisture reduction inhibits the growth of fly larvae | This is a true statement concerning moisture reduction |
| Absorbs moisture, ammonia, hydrogen sulphide and other gases | Non-Pesticidal |
| Inhibits the growth of Bacteria | Claim is allowed on non-public health products |
| Inhibits the growth of Fungi | Fungi is non-public health |
| Inhibits the growth of Viruses | A lesser claim for viruses than normal public health |
| Reduces Ammonia and Moisture. | Non-pesticidal |
| Bacteriostatic or bacteriostat | Non-public health claim allowed on non-public health products (EPA Reg. No. 35900-19) |
| Eliminates odor causing bacteria, fungi, mold, and mildew | Common non-public health claim |
| Eliminates odors associated with bacteria, mold, and mildew | Common non-public health claim |
| Deodorizer | Common non-public health claim |
| Controls and inhibits odor causing bacteria, fungi, mold, and mildew | Common non-public health claim |
| | |

Thank you in advance for reviewing these claims prior to the submission of our application. If there is any additional information I can provide in order to assist you, please do not hesitate to call me at 202-393-3903, ext. 20 or email me at bbrennis@lewisharrison.com.

Sincerely,

\S\
Robert S. Brennis
Agent for ArchAngel LLC

EPA

05-02-05

October 22, 2004

# EPA Meeting Notes
# October 12, 2004

ArchAngel LLC attended a meeting to establish the registration requirements for Stalosan F from the EPA. Those present were Bob Brennis, Kent Adams, Jan Storgaard, Glen Gabriel, and from the EPA were Tony Kish and Nancy White.

Topics:

1. Active ingredient identified as Copper Sulfate Pentahydrate. ArchAngel also supplied all of the CAS numbers for the ingredients used in Stalosan F. Nancy Whyte had an issue regarding whether all of the perfume ingredients were identified by EPA. She checked and found that all but one is identified.

2. ArchAngel presented the identities of two products that are registered by EPA with the use sites for animal confinement areas included. Tony appeared to confirm that this registration would be an old chemical registration with existing use sites.

3. The fact that this product is formulated with an unregistered source, will require the submission of full product chemistry data, and will include the citation or submission of generic data. As part of the chemistry data, ArchAngel will need to include formulation methods and a 5-batch analysis of the active ingredient contained in the product.

4. We also discussed the proposed label and found that we are not qualified for the claims that we have listed till we meet the non-porous surface claims "kill rate" of the 10-minute protocol. Some of the possible alternatives were discussed like moisture and mold control claims, as well as possible cross-contamination claims, or the adjunct claims, or the residual claims, or possibly claiming reducing bacterial and viral growth by reducing the moisture in the environment.

5. We spent considerable time on how the competitors are illegally listing claims for products without registrations. We discussed the Zorbisan advertisement and Tony and Nancy said they believed it to be a violation of the law.

6. Bob Brennis lead the discussion to confirm all that needs to be submitted and accepted to obtain a registration. Tony outlined the required submission material, which included the standard administration materials, full product chemistry, the

six-pack of acute toxicity data, and citation of generic data for the active ingredient. Also it was discussed that we may be eligible for a waiver of the $4,000 fee for registration due to volume of sales of ArchAngel.

7. Tony indicated that the timeframe for registration would be approximately a year. This would include generation of the data and two or three cycles for having to rework the registration paperwork to meet the EPA standards and resubmit our registration request. Each cycle would be 120 days for a non-fast track old chemical submission. It is reasonable to assume that if we get all of the submission correct, with only minor deficiencies, it would take only one cycle.

8. Tony asked that we submit a list of claims that we believe would be acceptable for this product, prior to the submission of the application. The discussion was predicated on the concept that we would obtain a registration without any public health claims on the label, although ArchAngel does have data that shows the product is efficacious when allowed to work beyond 10 minutes. Tony suggested that we may be able to use a "prevents cross-contamination between treated surfaces" claim. Nancy mentioned the claim "adjunct to manual disinfection". They also seemed to like the claim "lack of moisture assists in the reduction of microorganisms". ArchAngel is preparing a list and will submit it shortly to the Agency so that we can agree on what claims may be acceptable prior to submission of the application.

*Confidential Statement of Formula may be entitled to confidential treatment*